

# EXHIBIT I

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3                   CHARLESTON DIVISION

4 \_\_\_\_\_  
5   IN RE:   ETHICON, INC. PELVIC REPAIR       MDL 2327  
6           SYSTEMS PRODUCTS LIABILITY LITIGATION

7 \_\_\_\_\_  
8   MASTER FILE NO. 2:12-MD-02327

9 \_\_\_\_\_  
10   THIS DOCUMENT RELATES TO:  
11   JO'ANN LEHMAN v. ETHICON, INC., et al.  
12   Case No. 2:12-cv-517

13 \_\_\_\_\_  
14  
15  
16               PURSUANT TO NOTICE, the deposition of BRIAN  
17   FLYNN, M.D. was taken on behalf of the Plaintiff at  
18   Denver Marriott West, 1717 Denver West Boulevard,  
19   Boulder, Colorado on March 24, 2016, at 10:29 a.m.,  
20   before Melanie L. Giamarco, Registered Merit Reporter,  
21   Certified Realtime Reporter, and Notary Public within  
22   Colorado.

23  
24                   GOLKOW TECHNOLOGIES  
25                   877.370.3377 ph|917.591.5672 fax  
                  deps@golkow.com

Brian Flynn, M.D.

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<p>1 APPEARANCES</p> <p>2 For the Plaintiff Patricia Ruiz:</p> <p>3 JOSEPH ZONIES, ESQ.</p> <p>4 GREG BENTLEY, ESQ.</p> <p>5 ZONIES LAW, LLC</p> <p>6 1900 Wazee Street</p> <p>7 Suite 203</p> <p>8 Denver, Colorado 80202</p> <p>9 -and-</p> <p>10 MARY LIU, ESQ.</p> <p>11 AYLSTOCK, WITKIN, KREIS &amp; OVERHOLTZ, PLLC</p> <p>12 248 Third Street</p> <p>13 Suite 715</p> <p>14 Oakland, California 94607</p> <p>15 -and-</p> <p>16 D. RENEE BAGGETT, ESQ. (Present via telephone)</p> <p>17 AYLSTOCK, WITKIN, KREIS &amp; OVERHOLTZ, PLLC</p> <p>18 17 East Main Street</p> <p>19 Suite 200</p> <p>20 Pensacola, Florida 32502</p> <p>21 For the Defendants Johnson &amp; Johnson and Ethicon:</p> <p>22 KIM M. SCHMID, ESQ.</p> <p>23 JENNY A. COVINGTON, ESQ.</p> <p>24 BOWMAN AND BROOKE, LLP</p> <p>25 150 South Fifth Street</p> <p>Suite 3000</p> <p>Minneapolis, Minnesota 55402</p>	<p>1 PROCEEDINGS</p> <p>2 (Exhibit 1 was marked for identification.)</p> <p>3 BRIAN FLYNN, M.D.,</p> <p>4 after having been duly sworn, was examined and</p> <p>5 testified as follows:</p> <p>6 EXAMINATION</p> <p>7 BY MR. ZONIES:</p> <p>8 Q. Good morning, Dr. Flynn. My name's Joe</p> <p>9 Zonies. How are you this morning?</p> <p>10 A. Very good.</p> <p>11 Q. Good. Dr. Flynn, I've had marked</p> <p>12 Exhibit 1, and it's in front of you. And it's</p> <p>13 entitled "Amended Notice to Take Deposition of</p> <p>14 Brian Flynn, M.D."; do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Have you seen that document before?</p> <p>17 A. I have.</p> <p>18 Q. And when did you see that?</p> <p>19 A. Approximately one to two weeks ago.</p> <p>20 Q. Okay. And attached to this on page 6 is</p> <p>21 something -- on page, actually, 8 is Schedule A; do</p> <p>22 you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And have you reviewed Schedule A before?</p> <p>25 A. I have.</p>
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<p>1 INDEX</p> <p>2 EXAMINATION OF BRIAN FLYNN, M.D. PAGE</p> <p>3 March 24, 2016</p> <p>4 By Mr. Zonies 4, 100</p> <p>5 By Ms. Schmid 88</p> <p>6 EXHIBITS</p> <p>7 NUMBER DESCRIPTION PAGE</p> <p>8 Exhibit 1 Amended Notice to Take Deposition 4</p> <p>9 of Brian Flynn, M.D.</p> <p>10 Exhibit 2 Flash drive 6</p> <p>11 Exhibit 3 Expert Overview of TVT-Secur 6</p> <p>12 Exhibit 4 CV of Dr. Flynn 45</p> <p>13 Exhibit 5 Updated testimony list of Dr. Flynn 46</p> <p>14 Exhibit 6 Compilation of e-mails between Dr. 47</p> <p>15 Flynn and Ethicon</p> <p>16 Exhibit 7 Master Consulting Agreement 47</p> <p>17 Exhibit 8 Compilation of cover letters 50</p> <p>18 addressed to Dr. Flynn from Butler</p> <p>19 Snow, 8 pages</p> <p>20 Exhibit 9 Invoice for TVT-S report of Dr. 50</p> <p>21 Flynn</p> <p>22 Exhibit 10 JAMA scientific article entitled 55</p> <p>23 "Removal or revision of vaginal</p> <p>24 mesh used for the treatment of</p> <p>25 stress urinary incontinence."</p> <p>Exhibit 11 Cochrane collaboration paper 70</p> <p>entitled "Single incision sling</p> <p>operations for urinary incontinence</p> <p>in women (Review)"</p> <p>Exhibit 12 Study: TVT-Secur (Hammock) versus 84</p> <p>TVT-Obturator: A Randomized Trial</p> <p>of Suburethral Sling Operative</p> <p>Procedures</p>	<p>1 Q. And when did you review that?</p> <p>2 A. When I received it two weeks ago. And</p> <p>3 I've looked at it a number of times since then.</p> <p>4 Q. And have you done anything to collect</p> <p>5 the items that are requested in Exhibit A?</p> <p>6 A. I have.</p> <p>7 Q. Or Schedule A? Sorry.</p> <p>8 A. Yes.</p> <p>9 Q. Tell me what you collected.</p> <p>10 A. I have a USB drive here that has some</p> <p>11 presentations I've given on the TVT-Secur product.</p> <p>12 There is some Ethicon company documents on there,</p> <p>13 so it says the information for users. There is the</p> <p>14 patient brochures. There's a video, two different</p> <p>15 videos, one that was made by Ethicon, one that was</p> <p>16 made by me, so there's two videos on that USB.</p> <p>17 There's some pictures of the TVT-Secur product that</p> <p>18 were given to me by Ethicon. There are some</p> <p>19 Ethicon-prepared PowerPoints in regards to</p> <p>20 TVT-Secur on there. So that's what's on the USB.</p> <p>21 I may be missing a few items, but I think that's</p> <p>22 the majority.</p> <p>23 I've also brought my CV, my fee schedule, my</p> <p>24 deposition and trial history, my invoice on</p> <p>25 TVT-Secur. I have my expert report, and I have my</p>

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<p>1 reliance list and some supporting documents here.</p> <p>2 Q. Great. Now, have you updated your CV</p> <p>3 recently?</p> <p>4 A. I have. And it's -- the date is on the</p> <p>5 CV of when it was updated.</p> <p>6 MS. SCHMID: And I'm sorry to interrupt, but</p> <p>7 I don't think we got counsel's appearance on the</p> <p>8 record. Did we? I'd like to do that.</p> <p>9 MR. ZONIES: Joe Zonies and Greg Bentley on</p> <p>10 behalf of plaintiffs.</p> <p>11 MS. LIU: Mary Liu on behalf of Ms. Ruiz.</p> <p>12 MS. SCHMID: Kim Schmid from Bowman and</p> <p>13 Brooke in Minneapolis on behalf of the defendants</p> <p>14 Johnson &amp; Johnson and Ethicon.</p> <p>15 Q. (By Mr. Zonies) And, Doctor, could I</p> <p>16 get the flash drive, please? Thank you.</p> <p>17 MR. ZONIES: Go ahead and mark this as</p> <p>18 Exhibit 2.</p> <p>19 (Exhibit Number 2 was marked for</p> <p>20 identification.)</p> <p>21 Q. (By Mr. Zonies) Doctor, I'm handing you</p> <p>22 what's going to be marked as Exhibit 3.</p> <p>23 (Exhibit Number 3 was marked for</p> <p>24 identification.)</p> <p>25 Q. (By Mr. Zonies) Doctor, this was</p>	<p>1 Q. How many times have you implanted a</p> <p>2 TVT-Secur?</p> <p>3 A. Probably 175 times.</p> <p>4 Q. And how do you know that?</p> <p>5 A. I keep a case log of all implants that I</p> <p>6 do, both in men and women, and I have looked at</p> <p>7 that a number of times. I've prepared an abstract</p> <p>8 and a poster in the past on TVT-Secur, so certainly</p> <p>9 I reviewed my case log when I presented that</p> <p>10 abstract at a national meeting and when I prepared</p> <p>11 a video on TVT-Secur. So it's a log that the FDA</p> <p>12 also had recommended that physicians keep track of</p> <p>13 their implants, and so that's why I have that list.</p> <p>14 Q. And can you describe that log to me? Is</p> <p>15 it an Excel spreadsheet? How do you keep it?</p> <p>16 A. It's an Excel spreadsheet. It doesn't</p> <p>17 have just my TVT procedures. It's a list of all my</p> <p>18 patients. And so I do approximately 400 operations</p> <p>19 a year, and I've been keeping this log since 2004.</p> <p>20 It's also something that the American Board of</p> <p>21 Urology asks urologists to maintain a case log when</p> <p>22 we apply for board certification and</p> <p>23 recertification, so it's a running log that I've</p> <p>24 kept since I've been in practice.</p> <p>25 Q. And when's the last time you reviewed</p>
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<p>1 provided to us as your report, your expert report</p> <p>2 and opinions for TVT-Secur. Does this appear to be</p> <p>3 your report?</p> <p>4 A. (Reviewed document.) Yes, it does.</p> <p>5 Q. And it says it was dated February 26,</p> <p>6 2016. Is that when you executed or signed this</p> <p>7 report?</p> <p>8 A. Correct.</p> <p>9 Q. Do you have any updates to this report</p> <p>10 since you wrote it and submitted it?</p> <p>11 A. I do not.</p> <p>12 Q. Do you stand by what's in the report</p> <p>13 today?</p> <p>14 A. I do.</p> <p>15 Q. Do you understand, Doctor, that you're</p> <p>16 here today to testify -- well, can you tell me why</p> <p>17 you believe you're here today?</p> <p>18 A. I received this notice to take my</p> <p>19 deposition in regards to the TVT-Secur product.</p> <p>20 Q. And you are designated as an expert</p> <p>21 witness on behalf of Ethicon and J&amp;J for purposes</p> <p>22 of opining about the TVT-Secur; is that right?</p> <p>23 A. That's correct.</p> <p>24 Q. You personally have used the TVT-Secur?</p> <p>25 A. I have.</p>	<p>1 that log?</p> <p>2 A. I review it weekly, so last week.</p> <p>3 Q. And can you describe for me the cells in</p> <p>4 the Excel spreadsheet?</p> <p>5 A. Okay. Column 1 would have the patient's</p> <p>6 name. Column two would have medical record number,</p> <p>7 three would have the indication for the procedure,</p> <p>8 four would have the type of procedure. For</p> <p>9 practice-management standpoint, I usually keep</p> <p>10 track of who referred the patient to me and what</p> <p>11 town they're from. There probably is a few other</p> <p>12 columns on there, but it's just very basic</p> <p>13 information.</p> <p>14 I have other spreadsheets that I use for</p> <p>15 research purposes that would have more cells, you</p> <p>16 know, when I'm preparing a retrospective review</p> <p>17 that I might have other information on there in</p> <p>18 terms of the outcomes.</p> <p>19 Q. And where do you maintain these logs,</p> <p>20 spreadsheets?</p> <p>21 A. We have a server at the university, so I</p> <p>22 maintain them on the university server, which is</p> <p>23 protected and encrypted.</p> <p>24 Q. And do you also have copies of those on</p> <p>25 your local laptop?</p>

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<p>1 A. No.</p> <p>2 Q. Would it be difficult for you to produce</p> <p>3 those logs if we asked?</p> <p>4 MS. SCHMID: Objection; form.</p> <p>5 A. Yes, it's all HIPAA protected with</p> <p>6 private information, so I wouldn't be able to</p> <p>7 produce that.</p> <p>8 Q. (By Mr. Zonies) And it sounded to me</p> <p>9 like column A was the patient name, for example.</p> <p>10 Are there any other patient identifiers</p> <p>11 within those logs?</p> <p>12 A. The medical record number. I think</p> <p>13 their hometown, to some extent, identifies them and</p> <p>14 who their primary care physician is.</p> <p>15 Q. So if we requested that information</p> <p>16 absent patient-specific identifying</p> <p>17 characteristics, that's something that you</p> <p>18 effectively could just provide us a printout of,</p> <p>19 correct?</p> <p>20 MS. SCHMID: Objection; form.</p> <p>21 A. Not very --</p> <p>22 MS. SCHMID: Calls for -- excuse me.</p> <p>23 THE WITNESS: Sorry.</p> <p>24 MS. SCHMID: Calls for potentially</p> <p>25 confidential and privileged patient information.</p>	<p>1 Q. So it has -- that spreadsheet has</p> <p>2 implantations as well as revisions or explants?</p> <p>3 A. It has any surgical case I did.</p> <p>4 Q. Your 175 TVT-S procedures, are those</p> <p>5 implants?</p> <p>6 A. They had a mesh implant, yeah, the</p> <p>7 TVT-Secur.</p> <p>8 Q. And do you also know, as you sit here</p> <p>9 today, how many TVT-S products you've explanted, or</p> <p>10 revised?</p> <p>11 A. No. In terms of revisions I do, I</p> <p>12 mention the type of revision, but I don't keep</p> <p>13 track of what the product was necessarily. If I</p> <p>14 know what it is, I might record that, but most of</p> <p>15 the time, we don't know.</p> <p>16 Q. Do you undertake any steps prior to</p> <p>17 doing a revision or an explant to determine what</p> <p>18 device was originally implanted?</p> <p>19 A. Yes. I make all attempts to try to get</p> <p>20 the original operative report. That is relatively</p> <p>21 straightforward in getting. I'm probably able to</p> <p>22 get that about 75 percent of the time.</p> <p>23 Unfortunately, in the operative report, a lot of</p> <p>24 times they'll just say midurethral sling, or</p> <p>25 retropubic sling, or transobturator sling. So it</p>
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<p>1 Q. (By Mr. Zonies) Go ahead.</p> <p>2 A. It'd be very difficult.</p> <p>3 Q. Why is that?</p> <p>4 A. I think for the reasons that Kim just</p> <p>5 cited, because it's -- it's protected information.</p> <p>6 It would require a lot of editing of the</p> <p>7 spreadsheets to clean information off of those</p> <p>8 spreadsheets. All it would end up being is just a</p> <p>9 list of cases. It would be 175 cells that have</p> <p>10 TVT-Secur listed on it. I don't know what kind of</p> <p>11 value that would provide, but . . .</p> <p>12 Q. But, for example, that's something, if</p> <p>13 we said, provide us a spreadsheet with how many TVT</p> <p>14 products you've put in, that's -- you could run</p> <p>15 that out of that spreadsheet?</p> <p>16 MS. SCHMID: Objection; form.</p> <p>17 A. Not easily.</p> <p>18 Q. (By Mr. Zonies) Doctor, do you track</p> <p>19 your revision surgeries in a similar fashion?</p> <p>20 A. I do.</p> <p>21 Q. Is that a different spreadsheet?</p> <p>22 A. It's just one spreadsheet of all the</p> <p>23 cases, everything from kidney stones to</p> <p>24 incontinence surgery to kidney surgery. It's just</p> <p>25 one giant spreadsheet.</p>	<p>1 doesn't necessarily identify the product and</p> <p>2 certainly doesn't have the product sticker or</p> <p>3 anything that one could be a hundred percent</p> <p>4 confident on what the product was.</p> <p>5 Q. And when you do get that information, do</p> <p>6 you include that in your spreadsheet?</p> <p>7 A. I include it in the operative report.</p> <p>8 So in the operative report, it'll say -- if I knew</p> <p>9 it was a TVT-Secur, it would be listed in my</p> <p>10 operative report.</p> <p>11 Q. And do you have a sense, as you sit here</p> <p>12 today, of how many Securs you have either revised</p> <p>13 or explanted?</p> <p>14 A. No.</p> <p>15 Q. Do you -- more than ten? Or you just</p> <p>16 don't know at all?</p> <p>17 A. I would be guessing?</p> <p>18 Q. And is that something that if you went</p> <p>19 to your spreadsheets and you looked it up you might</p> <p>20 be able to give a better informed estimate rather</p> <p>21 than just a guess?</p> <p>22 A. Probably not.</p> <p>23 Q. Why not?</p> <p>24 A. Because the spreadsheet usually just</p> <p>25 lists the type of case. It'll say, for instance,</p>

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<p>1 "partial mesh removal," you know, so it doesn't</p> <p>2 necessarily say "partial removal of TVT-Secur." So</p> <p>3 the idea of the case log is something that just</p> <p>4 describes what the procedure was. If I was</p> <p>5 preparing a study, then I might get more</p> <p>6 information, more detail. But the case log, in</p> <p>7 order to keep it up to date and timely, I try to</p> <p>8 have a minimal amount of information in there, just</p> <p>9 what I feel is necessary information.</p> <p>10 Q. What was the time frame that you were</p> <p>11 using TVT-S?</p> <p>12 A. From 2007 to 2010.</p> <p>13 Q. Why did you stop?</p> <p>14 A. I switched to TVT-Abbrevio.</p> <p>15 Q. Why did you switch to TVT-Abbrevio?</p> <p>16 A. I was very interested in the product. I</p> <p>17 like trying new products. I tend to be the first</p> <p>18 person at my hospital or my community to use new</p> <p>19 products. And I liked the advantages of the</p> <p>20 TVT-Abbrevio over the TVT-Secur.</p> <p>21 Q. And what would those advantages be?</p> <p>22 A. The TVT-Abbrevio is a longer sling. I</p> <p>23 think it was an easier procedure to perform, to</p> <p>24 teach. And I think that the data is more</p> <p>25 supportive of a full-length sling, transobturator</p>	<p>1 Q. What was the average follow-up in that?</p> <p>2 A. Less than one year.</p> <p>3 Q. Have you ever done an analysis of those</p> <p>4 same patients in a midterm, say, two to three</p> <p>5 years?</p> <p>6 A. I have not done that personally in my</p> <p>7 patients, no.</p> <p>8 Q. Have any -- has anybody done that on</p> <p>9 your data?</p> <p>10 A. No.</p> <p>11 Q. You've never looked at the -- how many</p> <p>12 patients did you present in that paper?</p> <p>13 A. I believe that was the first 55, maybe</p> <p>14 60 patients that I did. It was a consecutive</p> <p>15 series, so those were the first 60 cases that I</p> <p>16 did.</p> <p>17 Q. Do you have any data on their one-year</p> <p>18 to two-year to three-year follow-up?</p> <p>19 A. Median follow-up in the study, as I</p> <p>20 mentioned, was less than one year, so there were</p> <p>21 some patients that were followed longer than one</p> <p>22 year, so for a few of those patients, I would have</p> <p>23 longer than one-year follow-up, but the average was</p> <p>24 one year.</p> <p>25 Q. And as you sit here today, do you have</p>
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<p>1 retropubic, so higher continence rates.</p> <p>2 Q. Of the 175 TVT implants that you</p> <p>3 performed, what kind of follow-up did you have on</p> <p>4 those patients?</p> <p>5 A. Typically I follow patients for one year</p> <p>6 after any implant. I usually see them at two</p> <p>7 weeks, six weeks, three months, and then at one</p> <p>8 year. And if at one year they're doing well and</p> <p>9 there's no other reason to follow them, then I</p> <p>10 usually discharge them from my practice at that</p> <p>11 point and tell them to come back as needed as long</p> <p>12 as they have someone else who can follow them in</p> <p>13 their community, their ob/gyn, their local</p> <p>14 urologist, their primary care physician.</p> <p>15 So I'll mention to them that they need an</p> <p>16 annual exam, and as part of the annual exam, they</p> <p>17 have should examine the prior surgical site, but I</p> <p>18 don't do that personally beyond one year.</p> <p>19 Q. You mentioned that you presented some of</p> <p>20 your TVT-S implant data at a meeting; is that</p> <p>21 right?</p> <p>22 A. That's correct.</p> <p>23 Q. And at that time, the data you presented</p> <p>24 was short-term follow-up; is that right?</p> <p>25 A. Correct.</p>	<p>1 any sense of the follow-up on those patients longer</p> <p>2 term?</p> <p>3 A. I have some sense. Many of those</p> <p>4 patients I've continued to follow for other</p> <p>5 indications, a prolapse, for instance, and they're</p> <p>6 patients that are in my practice. So of the 175</p> <p>7 patients probably in the last year, I've seen no</p> <p>8 more than 25 of them.</p> <p>9 Q. Have you ever performed any revisions on</p> <p>10 the TVT-S and any of those patients?</p> <p>11 A. Yes.</p> <p>12 Q. Do you have a sense of how many?</p> <p>13 A. I would say approximately ten.</p> <p>14 Q. And that's ten of the 175?</p> <p>15 A. Correct.</p> <p>16 Q. And what was the primary indication for</p> <p>17 which you revised those women?</p> <p>18 A. Recurring incontinence.</p> <p>19 Q. Would you agree that that means that the</p> <p>20 sling failed?</p> <p>21 MS. SCHMID: Objection; form, calls for a</p> <p>22 legal conclusion.</p> <p>23 A. No, I'd disagree.</p> <p>24 Q. (By Mr. Zonies) How would you describe</p> <p>25 recurrent incontinence?</p>



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<p>1 A. That the patient is now having leakage</p> <p>2 again of urine that is bothersome for them and that</p> <p>3 it is stress urinary incontinence. I usually will</p> <p>4 evaluate the patient with a history, physical,</p> <p>5 urodynamic evaluation. And if I can determine that</p> <p>6 it's urinary stress incontinence and it's</p> <p>7 bothersome to the patient, usually I'll institute</p> <p>8 some nonsurgical therapy, and if that doesn't work,</p> <p>9 then I'll discuss surgical therapy with them.</p> <p>10 Q. Well the purpose of the TVT-S in the</p> <p>11 first instance was to treat the stress urinary</p> <p>12 incontinence, correct?</p> <p>13 A. Correct.</p> <p>14 Q. And you had to revise these ten TVT-S's</p> <p>15 because they were not sufficiently treating this</p> <p>16 stress urinary incontinence, correct?</p> <p>17 MS. SCHMID: Objection; form, speculation.</p> <p>18 A. That's not correct.</p> <p>19 Q. (By Mr. Zonies) The ten --</p> <p>20 approximately ten women for whom you had to revise</p> <p>21 their TVT-S, is that a subgroup of the 25 women</p> <p>22 that you said you continue to follow?</p> <p>23 A. They would be included in the 25. Well,</p> <p>24 that's hard to say. I mentioned earlier there's 25</p> <p>25 patients that I've probably seen recently. Some of</p>	<p>1 Q. Okay. Maybe I misheard you, and that</p> <p>2 was a whole line of questioning that we need to go</p> <p>3 back and revisit, which is, you said that of the</p> <p>4 original 60 women in your cohort, between five and</p> <p>5 six of those women you needed to do a revision</p> <p>6 surgery on, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And what was the indication for the</p> <p>9 revision surgery in those five to six women?</p> <p>10 A. Either bladder incomplete emptying or</p> <p>11 urinary retention, so the sling was too tight. I</p> <p>12 had to go back and loosen it.</p> <p>13 Q. Do you have a sense as of today in that</p> <p>14 original cohort how many failures of the TVT-S you</p> <p>15 had?</p> <p>16 MS. SCHMID: Objection; form, calls for a</p> <p>17 legal conclusion.</p> <p>18 Go ahead.</p> <p>19 A. You would have to be more specific on</p> <p>20 what you would define as "failure."</p> <p>21 Q. (By Mr. Zonies) Okay. So of those 60</p> <p>22 women, how many of those women did you have to</p> <p>23 perform a subsequent surgery on for -- related to</p> <p>24 their TVT-S?</p> <p>25 A. Well, in the time period that I followed</p>
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<p>1 these patients I treated as early as 2007. If they</p> <p>2 had recurring incontinence, say, in 2008, I may</p> <p>3 have treated that and then followed them to 2009,</p> <p>4 and they might not be in that 25. So it would just</p> <p>5 depend on when the recurrence was.</p> <p>6 Q. Is it that data that you have available</p> <p>7 to you which patients and how many and when you had</p> <p>8 to do a revision?</p> <p>9 A. Of that original 60 patients or so that</p> <p>10 I mentioned in the abstract, there's a few patients</p> <p>11 in there that were included, but beyond that cohort</p> <p>12 that I followed for that study, no.</p> <p>13 Q. Do you know how many of the 60 in your</p> <p>14 original cohort you needed to do a revision surgery</p> <p>15 on?</p> <p>16 A. I believe there was approximately five</p> <p>17 or six patients. I would have to look at the</p> <p>18 abstract again for the exact number.</p> <p>19 Q. Is it fair to say roughly 10 percent of</p> <p>20 your TVT-S patients in that original cohort needed</p> <p>21 a revision surgery for recurrent incontinence?</p> <p>22 A. No, there was nobody who had revisions</p> <p>23 for recurrent incontinence. Those were revisions</p> <p>24 for urinary retention and bladder incomplete</p> <p>25 emptying.</p>	<p>1 those patients for that study, I had five</p> <p>2 revisions. They were for all the -- either</p> <p>3 incomplete emptying or retention. The success rate</p> <p>4 that I reported in that study was around 85</p> <p>5 percent. So that would imply that about seven</p> <p>6 patients had recurrent incontinence, but at least</p> <p>7 at the time of that study, I hadn't re-operated on</p> <p>8 those patients, those seven that had recurrent</p> <p>9 incontinence. I may have at future dates, but that</p> <p>10 wasn't part of that study.</p> <p>11 Q. And have you ever done any analysis of</p> <p>12 these -- this cohort more recently than when you</p> <p>13 did your presentation?</p> <p>14 A. No.</p> <p>15 Q. Why not?</p> <p>16 A. I do 500 surgeries a year. I've been</p> <p>17 doing that for 15 years. There's no possible way I</p> <p>18 could do a study on every single patient I operate</p> <p>19 on. There's just too many patients. So</p> <p>20 periodically, I'll look at my case log. If I</p> <p>21 notice any trends or anything that seems to be</p> <p>22 concerning to me, I may look at that more closely,</p> <p>23 but if I have to re-operate on ten people out of</p> <p>24 175 for incontinence, I'm very happy with that. I</p> <p>25 think that's a great result, and so I don't see a</p>

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<p>1 need to look at those patients.</p> <p>2 Q. But as you're sitting here today, you</p> <p>3 can't tell me how many of those 60 women you have</p> <p>4 ever re-operated on, correct?</p> <p>5 A. I think what I mentioned, of those 60,</p> <p>6 and for the time period that I studied them, I</p> <p>7 re-operated on five. Beyond the time period for</p> <p>8 that study, I can't give you an exact number.</p> <p>9 Q. Can you give me an estimate?</p> <p>10 A. I would say the estimate is probably</p> <p>11 somewhere around 5 percent. You know, we did -- I</p> <p>12 mentioned earlier about ten of the 175 patients I</p> <p>13 may have to have re-operated or for incontinence.</p> <p>14 Of that ten, some of them might have been the five</p> <p>15 that I had to go and loosen the sling up. I don't</p> <p>16 know. There's some overlap. The numbers aren't</p> <p>17 necessarily additive. But I would say my revision</p> <p>18 rate for TVT-Secur was maybe only slightly higher</p> <p>19 than what it was for full-length slings.</p> <p>20 Q. And what about other adverse outcomes?</p> <p>21 MS. SCHMID: Objection; form.</p> <p>22 A. Can you give me an example of what you</p> <p>23 mean by "other adverse outcomes"?</p> <p>24 Q. (By Mr. Zonies) What about exposures?</p> <p>25 A. In that original cohort of 60 patients,</p>	<p>1 A. If we're going to spend a lot of time on</p> <p>2 this, I'd like to have the study in front of me.</p> <p>3 MS. SCHMID: Go ahead and find it.</p> <p>4 THE WITNESS: Okay.</p> <p>5 Q. (By Mr. Zonies) But my question,</p> <p>6 Doctor, is, subsequent --</p> <p>7 MS. SCHMID: Just a minute. Dr. Flynn is</p> <p>8 looking for the study.</p> <p>9 MR. ZONIES: No, no, no, my -- I'm going to</p> <p>10 clarify something.</p> <p>11 Q. (By Mr. Zonies) Doctor, my question is,</p> <p>12 subsequent to the study -- I understand what the</p> <p>13 study says. I'm asking, subsequent to the study,</p> <p>14 how many exposures did those 60 women have?</p> <p>15 A. Yeah, I think, as I mentioned, about one</p> <p>16 patient that I can think of. One patient.</p> <p>17 Q. And --</p> <p>18 MS. SCHMID: And, Dr. Flynn, if you would</p> <p>19 like to pull up your study so you've got the</p> <p>20 numbers in front of you, please go ahead and do so.</p> <p>21 Q. (By Mr. Zonies) And how do you know</p> <p>22 just one patient subsequent to the study?</p> <p>23 A. That's based on recall. That's based on</p> <p>24 me following my patients, so that's -- that's how I</p> <p>25 base it on.</p>
Page 23	Page 25
<p>1 we didn't have a single exposure.</p> <p>2 Q. Ever? Even up to today?</p> <p>3 A. Just for the time period that we studied</p> <p>4 those patients.</p> <p>5 Q. And do you have any data on whether or</p> <p>6 not there was an exposure subsequent to that time</p> <p>7 frame?</p> <p>8 A. Of the 175 patients, I could think of</p> <p>9 possibly one exposure. It was very rare that</p> <p>10 TVT-Secur ever became exposed in the patients I</p> <p>11 treated. The most common reason for revision was</p> <p>12 reoccurring incontinence. That was the ten</p> <p>13 patients that I mentioned. And these are</p> <p>14 approximate numbers.</p> <p>15 Q. So let's talk -- I want to talk about</p> <p>16 the 60 -- your original cohort of 60, not the 175</p> <p>17 for a minute, okay?</p> <p>18 A. Okay.</p> <p>19 Q. Of the 60 women that you originally</p> <p>20 operated on with TVT-S and that you reported on at</p> <p>21 a conference, how many of those women ever had an</p> <p>22 exposure?</p> <p>23 A. Of the 60, zero. There was not a single</p> <p>24 exposure in that study.</p> <p>25 Q. What --</p>	<p>1 Q. And of those 60 women in your original</p> <p>2 cohort subsequent to your reporting on the study,</p> <p>3 how many of them needed a revision to their TVT-S</p> <p>4 sling?</p> <p>5 A. Are you asking me what the overall</p> <p>6 revision rate I had in the 175 patients? Is that</p> <p>7 the question?</p> <p>8 Q. I'm asking about the 60 women in your</p> <p>9 original cohort that you reported on subsequent to</p> <p>10 your study. How many of those 60 women needed a</p> <p>11 revision to their TVT-S?</p> <p>12 A. I don't know the answer to that.</p> <p>13 Q. Dr. Flynn, what's your current position</p> <p>14 at the University of Colorado?</p> <p>15 A. I'm an associate professor of surgery</p> <p>16 and urology. I am the co-practice director of the</p> <p>17 Women's Pelvic Health and Surgery Clinic. I'm a</p> <p>18 fellowship director in reconstructive urology. So</p> <p>19 those are my titles.</p> <p>20 Q. How long have you been an associate</p> <p>21 professor?</p> <p>22 A. Since 2008. And I'm up for promotion</p> <p>23 this year. And I hope to be promoted to full</p> <p>24 professor in July of this year.</p> <p>25 Q. Have you ever been up for a promotion to</p>



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<p>1 full professor before?</p> <p>2 A. No. This is the first time.</p> <p>3 Q. In your report, Dr. Flynn, on page 21,</p> <p>4 if you could turn to that, please.</p> <p>5 A. Okay.</p> <p>6 MR. BENTLEY: Sorry to interrupt. I don't</p> <p>7 think the phone --</p> <p>8 MR. ZONIES: Why don't we take a break.</p> <p>9 (A recess was taken from 10:59 a.m. until</p> <p>10 11:01 a.m.)</p> <p>11 MS. SCHMID: Can we note for the record</p> <p>12 appearance by telephone by counsel?</p> <p>13 MS. BAGGETT: Sure. Renee Baggett.</p> <p>14 MR. ZONIES: Anybody other than Renee?</p> <p>15 (No audible response.)</p> <p>16 Q. (By Mr. Zonies) So Dr. Flynn, just -- I</p> <p>17 just want to be clear on this. Subsequent to</p> <p>18 presenting your TVT-S paper, you have not</p> <p>19 undertaken any formal efforts or analysis of those</p> <p>20 60 patients to see how they're doing today or in</p> <p>21 any time since presentation of that paper, correct?</p> <p>22 A. Not a formal analysis, correct.</p> <p>23 Q. Have you done any informal analysis of</p> <p>24 those 60 patients?</p> <p>25 A. Yeah, I think the informal analysis, as</p>	<p>1 A. That's the approximate date. I believe</p> <p>2 that's close, 2007.</p> <p>3 Q. And when you first started to use the</p> <p>4 TVT-S, what were you using prior to that?</p> <p>5 A. TVT and TVT Obturator.</p> <p>6 Q. Did you stop using TVT and TVT Obturator</p> <p>7 when you switched to TVT-S?</p> <p>8 A. No.</p> <p>9 Q. How would you choose which device to</p> <p>10 use?</p> <p>11 A. Any time I'm using a new device, I'm</p> <p>12 very selective in who I offer that to. Gradually,</p> <p>13 as I gain confidence in the procedure, I tend to</p> <p>14 use it more commonly in my practice, so there's</p> <p>15 always a transition period between a new product</p> <p>16 and a previous product. And if you find that</p> <p>17 there's patients that you can't treat effectively</p> <p>18 with the new product you're using but there's</p> <p>19 advantages to that new product for most patients,</p> <p>20 then I would continue to perform the procedures I</p> <p>21 was doing before that.</p> <p>22 So for instance, patients with recurring</p> <p>23 incontinence, patients with intrinsic sphincter</p> <p>24 deficiency, patients that I felt needed a greater</p> <p>25 degree of support, then I prefer today, and then,</p>
Page 27	Page 29
<p>1 I mentioned, were the ten or so patients that I had</p> <p>2 to re-operate on for recurrent incontinence that</p> <p>3 came back to me. But there's patients, of course,</p> <p>4 that -- you know, that I haven't seen in many</p> <p>5 years, so I mentioned the patients that are doing</p> <p>6 well, I just follow for one year.</p> <p>7 Q. So there's -- you don't know, for</p> <p>8 example, of the 50 women that you haven't had back</p> <p>9 for a revision, how many of those women needed</p> <p>10 revision or subsequently suffered from an exposure</p> <p>11 or needed some other operation. You just don't</p> <p>12 know that, correct?</p> <p>13 MS. SCHMID: Objection; form, foundation,</p> <p>14 argumentative.</p> <p>15 Go ahead.</p> <p>16 A. Like I mentioned earlier, there's</p> <p>17 patients that I haven't followed beyond one year.</p> <p>18 That's the majority of patients I have not followed</p> <p>19 beyond one year.</p> <p>20 Q. (By Mr. Zonies) Okay. So the majority</p> <p>21 of the women in that cohort of 60 women you have</p> <p>22 not followed beyond one year, correct?</p> <p>23 A. Correct.</p> <p>24 Q. You started to use the TVT-S, you said,</p> <p>25 in 2007; is that right?</p>	<p>1 and I've always preferred the retropubic TVT.</p> <p>2 Q. So I want to -- I appreciate that.</p> <p>3 I want to talk specifically about this time</p> <p>4 frame, in 2007, to the best of your recollection,</p> <p>5 when you started to use the TVT-S.</p> <p>6 How were you making your decisions whether</p> <p>7 or not to use a TVT-S versus a TVT or a TVT-O?</p> <p>8 A. So during 2007, I was using all three</p> <p>9 products. By 2008, TVT-S became the predominant</p> <p>10 product that I was using in my practice as I gained</p> <p>11 a better understanding of who it was effective on</p> <p>12 and I gained confidence from seeing patients coming</p> <p>13 back to me that were doing well, having no</p> <p>14 complications, having good bladder control, and</p> <p>15 enjoying the benefits of a minimally invasive</p> <p>16 procedure.</p> <p>17 So once I gained confidence that this</p> <p>18 procedure was going to perform well, I noticed</p> <p>19 immediately that patients were having minimal</p> <p>20 recovery and returning to work within a week, I</p> <p>21 began to offer it to a wider variety of patients.</p> <p>22 Between 2008 and 2010, there were select patients</p> <p>23 that I continued to do the retropubic or the</p> <p>24 Obturator procedure on.</p> <p>25 Q. And what was the -- what was different</p>

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<p>1 with the patients where you decided to use TVT or</p> <p>2 TVT Obturator?</p> <p>3 A. If someone came to me who had a prior</p> <p>4 failed incontinence procedure, I was more inclined</p> <p>5 to offer them the retropubic procedure or the</p> <p>6 transobturator procedure just because there's more</p> <p>7 data on that procedure and longer follow-up, so I</p> <p>8 tended to go with a more time-tested procedure as</p> <p>9 long as the patient was willing. I mentioned to</p> <p>10 them that there was greater risk with those</p> <p>11 procedures and greater recovery.</p> <p>12 So, as I do with all my patients, I have an</p> <p>13 informed discussion about the risks and benefits of</p> <p>14 the procedure. I discuss alternatives, and we make</p> <p>15 a mutual decision with the patient.</p> <p>16 There are certain patients that prefer to</p> <p>17 have the most efficacious procedure regardless of</p> <p>18 risk. They have more risk tolerance. Others are</p> <p>19 more driven by data. They've gone through the</p> <p>20 medical literature themselves on websites or things</p> <p>21 that I've provided to them, and they selected the</p> <p>22 retropubic procedure or the transobturator</p> <p>23 procedure, for instance.</p> <p>24 I would say, overwhelmingly, the patients</p> <p>25 tend to go with what my recommendation was. And so</p>	<p>1 the TVT-O and the TVT-S; is that fair?</p> <p>2 A. That was part of the discussion. I</p> <p>3 mentioned the benefits as well.</p> <p>4 Q. Right. And another one was the</p> <p>5 difference in benefits between the three devices,</p> <p>6 correct?</p> <p>7 A. Correct.</p> <p>8 Q. So -- and it sounds like you would also</p> <p>9 have a discussion with the patient about the</p> <p>10 differences in how the three devices would treat</p> <p>11 specific types of stress urinary incontinence,</p> <p>12 correct?</p> <p>13 A. Correct.</p> <p>14 Q. So for example, one of the differences</p> <p>15 between the three devices that you would discuss</p> <p>16 was the -- if you felt that the patient needed more</p> <p>17 support, you would not necessarily recommend the</p> <p>18 TVT-Secur, correct?</p> <p>19 A. I would still discuss the TVT-Secur as</p> <p>20 an option, but I would encourage them, if the level</p> <p>21 of risk was acceptable, to choose the full-length</p> <p>22 procedure.</p> <p>23 Q. And I understand -- well, was there ever</p> <p>24 a time in this -- let me start that again.</p> <p>25 Do you recall whether you would have</p>
Page 31	Page 33
<p>1 if I identified someone that I felt needed more</p> <p>2 support, for instance, they've had a prior failed</p> <p>3 incontinence procedure, they had intrinsic</p> <p>4 sphincter deficiency, I would be more inclined to</p> <p>5 go with the full-length sling, either retropubic or</p> <p>6 transobturator.</p> <p>7 The difference between retropubic and</p> <p>8 transobturator, if I felt that placing the</p> <p>9 retropubic sling was going to be difficult because</p> <p>10 of prior surgeries, then I would select the</p> <p>11 transobturator procedure. But, you know, during</p> <p>12 that time period, most of the cases were TVT-Secur,</p> <p>13 and then there was a smaller percentage for</p> <p>14 retropubic and obturator, that was about equal.</p> <p>15 Q. So when you were having a discussion</p> <p>16 with a patient in that time frame, was your</p> <p>17 discussion -- or did -- strike that.</p> <p>18 When you were having a discussion with a</p> <p>19 patient in that time frame, it sounds like you</p> <p>20 differentiated between devices for -- to help the</p> <p>21 patient understand the devices; is that fair?</p> <p>22 A. Correct.</p> <p>23 Q. And so some of the differences that you</p> <p>24 would discuss with the patients, it sounds like,</p> <p>25 were the different risks associated with the TVT,</p>	<p>1 discussions with patients in this time frame where</p> <p>2 you would specifically not recommend one of the</p> <p>3 three devices?</p> <p>4 MS. SCHMID: Objection; form.</p> <p>5 Go ahead.</p> <p>6 A. There may be a rare patient that I would</p> <p>7 have objected for one of those. I try to present</p> <p>8 all three devices and the risks and benefits of</p> <p>9 each. If they chose an option that I didn't feel</p> <p>10 strongly about, then I would heavily discourage</p> <p>11 them from choosing that option. And usually they</p> <p>12 would, you know, accept my opinion, my</p> <p>13 recommendation.</p> <p>14 Q. So can you give me a general idea of</p> <p>15 what your discussion was with patients about the</p> <p>16 differences between the TVT-Secur and the other two</p> <p>17 choices, the TVT and the TVT-O?</p> <p>18 A. So what I would mention to them is that</p> <p>19 the TVT device is the device that was the original</p> <p>20 device. It came to the United States in around</p> <p>21 1998. It was the most widely studied device for</p> <p>22 stress urinary incontinence ever. And so there was</p> <p>23 a wealth of data behind that device. It was a very</p> <p>24 time-tested procedure with a predictable outcome</p> <p>25 and known complications.</p>

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<p>1 The TVT-Secur device was a newer device,  2 more recently FDA approved. I mentioned to the  3 patients that there was less data on the device,  4 but at least my preliminary results in that 60  5 patients or so I was following prospectively were  6 doing well, and they were able to have surgery  7 without having a general anesthesia. They were  8 able to go home the same day. They didn't require  9 a Foley catheter. Usually they can go back to work  10 within a week. And I hadn't noticed any  11 significant complications, except the few patients  12 I mentioned with urinary retention.</p> <p>13 So it was performing very well. And so --  14 but I did mention that these were early results. I  15 try to help patients understand the difference  16 between early, midterm and long-term results, and  17 then, you know, ultimately, let them decide at that  18 time point.</p> <p>19 Q. So one of the differences that you would  20 discuss with your patients between the TVT-S and  21 the TVT device was that there was less data  22 available for the TVT-S, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And that the results that you had on  25 your -- on the TVT-S were early results as compared</p>	<p>1 after the retropubic. But once I started doing  2 both procedures, I did discuss them together.</p> <p>3 Q. Why did you think it was important to  4 tell your patients that there was a difference in  5 the available data between the TVT and the TVT-S?</p> <p>6 A. Because that's part of the informed  7 consent. That's what we're taught in residency and  8 in medical school, that when you're going to obtain  9 an informed consent from the patient, your job is  10 to try to educate them on what the literature shows  11 and what your own personal experience has been with  12 the device.</p> <p>13 Q. I asked you to turn to page, I think, 21  14 of your report. Do you have that before you?</p> <p>15 MS. SCHMID: Sorry, Joe, which page?</p> <p>16 MR. ZONIES: 21 of Exhibit 3.</p> <p>17 MS. SCHMID: Thank you.</p> <p>18 A. Yes, I see the picture of the TVT-Secur  19 device. Is that the page?</p> <p>20 Q. (By Mr. Zonies) Correct.</p> <p>21 A. Yes.</p> <p>22 Q. When you would have discussions with  23 your patients, would you show them photos of the  24 different devices?</p> <p>25 A. Yes.</p>
Page 35	Page 37
<p>1 to the TVT, which had, at that point, years of  2 results available, correct?</p> <p>3 A. Correct.</p> <p>4 Q. Would you also discuss with your  5 patients the differences between the TVT-Secur and  6 the TVT Obturator?</p> <p>7 A. I tended to discuss the full-length  8 slings together as a group since they performed  9 very similarly, and then the TVT-Secur. It's  10 difficult when you're discussing too many options  11 with the patients. I think it becomes overwhelming  12 and hard to make a decision. So if you have  13 options that are similar, I tend to present them  14 together. So I would present the conversation as a  15 full-length sling versus a mini sling. If they  16 choose the full-length sling, then I might go into  17 the nuances of the differences between those two  18 products.</p> <p>19 Q. And so prior to 2007 when you started to  20 use a TVT-Secur, for example, your conversations  21 may actually be more focused on the differences  22 between the TVT and the TVT Obturator; is that  23 fair?</p> <p>24 A. Correct. I started doing the TVT  25 Obturator later in my practice, but before Secur,</p>	<p>1 Q. Would you describe the device using the  2 photograph for your patients?</p> <p>3 A. That was part of the conversation. Not  4 all patients wanted to see that, but patients asked  5 and said, "Do you have a picture of this," or "Do  6 you have the actual device with you, can I see it?"  7 So for some patients, I would just show them a  8 photo of the device in the brochure, for instance.  9 And for others, if they wanted to feel it, touch  10 it, I had a sample of the TVT-Secur, of all the  11 meshes, and I would put the device right in their  12 hand so they can touch it.</p> <p>13 Q. The picture of the TVT-Secur that's on  14 page 21 of your report, where did you get that  15 picture for your report? Do you know?</p> <p>16 A. That's a picture from the brochure. So  17 you can see in the corner there, I think it was a  18 picture that I just cropped out of the patient  19 brochure.</p> <p>20 Q. And --</p> <p>21 A. Or, I'm sorry, either out of that or  22 maybe out of the IFU, but somewhere from the  23 Ethicon literature that was provided to me, maybe a  24 PowerPoint presentation.</p> <p>25 Q. Looking at this device and with your</p>

<p style="text-align: right;">Page 38</p> <p>1 experience with the TVT and TVT Obturator -- well,</p> <p>2 let's start with the TVT.</p> <p>3 So looking at the photograph on page 21, and</p> <p>4 based on your experience using the TVT-Secur and</p> <p>5 the TVT, how would you describe the differences</p> <p>6 between the TVT-Secur and the TVT?</p> <p>7 MS. SCHMID: Objection; form.</p> <p>8 Go ahead.</p> <p>9 A. The primary difference is the length of</p> <p>10 the sling and the inserter. Those were the primary</p> <p>11 differences, and then the fleece at the tips. So</p> <p>12 those were the three big differences, the length of</p> <p>13 the mesh, the PDS Vicryl fleece at the tip, and</p> <p>14 then the difference in the inserter.</p> <p>15 Q. (By Mr. Zonies) And when you say "the</p> <p>16 difference in the inserter," what do you mean?</p> <p>17 A. So with TVT and TVT Obturator, we use</p> <p>18 the word "trocar." There's a trocar that's used to</p> <p>19 tunnel the device. With the Secur, there's no</p> <p>20 actual trocar. There's no exit point. This is a</p> <p>21 single-incision sling procedure, and so the</p> <p>22 inserter is -- the majority of what you see in the</p> <p>23 picture, it's the metal device with the plastic</p> <p>24 tab, the finger pad, so the majority of what you're</p> <p>25 seeing there, there's two inserters, one for the</p>	<p style="text-align: right;">Page 40</p> <p>1 point.</p> <p>2 With mini slings, TVT-Secur included</p> <p>3 American Medical Systems' MiniArc, Boston</p> <p>4 Scientific Solyx. There's some sort of anchor at</p> <p>5 the tip that will create fixation. So the</p> <p>6 difference between mini slings and the full-length</p> <p>7 slings is not only the length, it's the way they're</p> <p>8 fixated.</p> <p>9 Over time, the PDS and Vicryl will go away,</p> <p>10 so the fixation mechanism is really the mesh just</p> <p>11 like it is with the full-length sling, but at least</p> <p>12 short-term, the fixation -- the fleece and the PDS</p> <p>13 is like cotton. It's sticky, and so it allows the</p> <p>14 mesh to fixate to the surrounding tissue.</p> <p>15 Q. And with your experience with TVT-S --</p> <p>16 let me ask this, Doctor: Did you experience a</p> <p>17 difference in outcomes associated with the</p> <p>18 difference in fixation between the TVT and the</p> <p>19 TVT-S?</p> <p>20 MS. SCHMID: Objection; form.</p> <p>21 Go ahead.</p> <p>22 A. There was a difference in outcomes</p> <p>23 between the full-length slings and the mini slings.</p> <p>24 Why there was a difference? Was that the length of</p> <p>25 the sling or the fixation mechanism? I don't know</p>
<p style="text-align: right;">Page 39</p> <p>1 right, one for the left, and then the mesh is in</p> <p>2 the middle with the PDS Vicryl fleece at the tip.</p> <p>3 Q. And what difference, to you clinically,</p> <p>4 did the fleece make?</p> <p>5 A. Difference with respect to other</p> <p>6 products or . . .</p> <p>7 Q. Comparing the -- again, I'm still stuck</p> <p>8 on comparing the TVT-Secur to the TVT.</p> <p>9 The TVT-Secur, as you point out, has fleece</p> <p>10 on the tips of the mesh, correct?</p> <p>11 A. Correct.</p> <p>12 Q. And you said that that's a Vicryl</p> <p>13 fleece?</p> <p>14 A. It's a mixture of Vicryl and PDS.</p> <p>15 Q. And what was your understanding of why</p> <p>16 that was on the TVT-Secur, and how did it impact</p> <p>17 your clinical approach to the TVT-Secur?</p> <p>18 MS. SCHMID: Objection; foundation.</p> <p>19 Go ahead.</p> <p>20 A. So any of the midurethral slings are</p> <p>21 going to have various ways of having fixation. So</p> <p>22 you need to have a way of fixating the mesh.</p> <p>23 With the full-length sling, the fixation is</p> <p>24 the mesh. The mesh will grab onto all of the</p> <p>25 surrounding tissue so there's no anchor or fixation</p>	<p style="text-align: right;">Page 41</p> <p>1 the answer to the second part of your question, but</p> <p>2 the first part is, yeah, clinically, I did see a</p> <p>3 difference in terms of the continence outcome.</p> <p>4 Q. And is that something you would discuss</p> <p>5 with your patients?</p> <p>6 A. Yeah. Getting back to what I said</p> <p>7 earlier, part of the informed consent is what the</p> <p>8 available literature shows, what your personal</p> <p>9 experience is. So when I started with the device,</p> <p>10 I told the patients, I don't have a lot of personal</p> <p>11 experience with the device, and so we really don't</p> <p>12 know how this is going to perform in my hands, but</p> <p>13 I can tell you how it's performed in other people's</p> <p>14 hands. And then as you gain experience with a</p> <p>15 device, you start to share your own results with</p> <p>16 your patients. And I did mention to them that it</p> <p>17 was a less-robust procedure when compared to the</p> <p>18 full-length slings.</p> <p>19 Q. And what did you mean when you described</p> <p>20 to them that it was a less-robust procedure?</p> <p>21 A. That the continence outcomes were</p> <p>22 inferior.</p> <p>23 Q. And the continence outcomes were</p> <p>24 inferior as compared to the TVT and the TVT-O?</p> <p>25 A. Correct.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q. When you were looking at the picture of</p> <p>2 the TVT-Secur on page 21, you also discussed one of</p> <p>3 the differences between the TVT-S and the TVT and</p> <p>4 TVT-O is that the TVT-S has the inserters you</p> <p>5 described as most of what we're seeing in the</p> <p>6 picture; is that right?</p> <p>7 A. Yes.</p> <p>8 Q. And what would you discuss with the</p> <p>9 patient between 2007 and 2010 about the impact of</p> <p>10 the inserters on the surgery?</p> <p>11 MS. SCHMID: Objection; form.</p> <p>12 Go ahead.</p> <p>13 A. At that point, that's getting a little</p> <p>14 too specific with what I'm doing in surgery. I</p> <p>15 don't mention to them what type of suture I use to</p> <p>16 close their wound, what kind of dressing I'm going</p> <p>17 to use, what kind of catheter I'm going to use.</p> <p>18 There's only a finite amount of time you can spend</p> <p>19 with the patient.</p> <p>20 So I would share with them what I felt were</p> <p>21 the important differences, which was the length of</p> <p>22 the sling and the cotton fleece at the tip, and</p> <p>23 that it wasn't as a well-studied device as the</p> <p>24 full-length sling. Those were the things that I</p> <p>25 felt were important in the conversation, in</p>	<p style="text-align: right;">Page 44</p> <p>1 impact your clinical outcome's efficacy or risks?</p> <p>2 A. No.</p> <p>3 Q. You didn't believe there was any benefit</p> <p>4 being derived from it being a single incision?</p> <p>5 MS. SCHMID: Objection; form.</p> <p>6 Go ahead.</p> <p>7 A. I do believe there was benefits from the</p> <p>8 single incision, yes.</p> <p>9 Q. (By Mr. Zonies) What would you describe</p> <p>10 to your patients as the benefits associated with a</p> <p>11 single incision?</p> <p>12 A. Primarily that it's a less invasive</p> <p>13 procedure, so you have one incision instead of one</p> <p>14 incision and two punctures. There's less</p> <p>15 dissection, less anesthetic requirements, less</p> <p>16 recovery, less convalescence, less chance of</p> <p>17 injuring surrounding structures such as the bladder</p> <p>18 or bowel or major vascular structures or nerves,</p> <p>19 and so overall, because it was small, it was mini,</p> <p>20 and there was less tunnelling, that it was a safer</p> <p>21 procedure.</p> <p>22 Q. And you told your patients that it was a</p> <p>23 safer procedure, that there were -- you had</p> <p>24 beneficial risk profiles associated with the TVT-S</p> <p>25 than with the TVT or TVT-O?</p>
<p style="text-align: right;">Page 43</p> <p>1 addition to the procedure being less invasive, less</p> <p>2 recovery, less convalescence, the ability to do it</p> <p>3 under a local anesthesia, IV sedation.</p> <p>4 So I generally talked to them about what the</p> <p>5 recovery would be like, how long their surgery</p> <p>6 would be, what the risks and benefits were, and</p> <p>7 what the expected outcome, but I wouldn't get into</p> <p>8 too much detail on how the device was placed inside</p> <p>9 their body, whether it was a mini sling or a</p> <p>10 retropubic or obturator. The inserter part, I</p> <p>11 think, is less important to the patient.</p> <p>12 Q. For you clinically, did the inserter</p> <p>13 impact your outcomes, either efficacy or risk?</p> <p>14 A. No.</p> <p>15 Q. What about the release wire and the</p> <p>16 release mechanism in the TVT-S, did you find that</p> <p>17 that impacted your clinical outcomes or risk?</p> <p>18 A. No.</p> <p>19 Q. What about the fact that it was a single</p> <p>20 incision as compared to a multiple-incision device,</p> <p>21 did you feel that that impacted your clinical</p> <p>22 outcomes or clinical risks?</p> <p>23 Let me ask it this way: Did you find the</p> <p>24 fact that it was a single-incision sling as</p> <p>25 compared to the multi-incision slings -- did that</p>	<p style="text-align: right;">Page 45</p> <p>1 A. Correct.</p> <p>2 Q. So I don't want -- let me ask it this</p> <p>3 way, Doctor: Would it be fair to say that you</p> <p>4 believe that the TVT-S as compared to the TVT, that</p> <p>5 the TVT-S was less efficacious but provided some</p> <p>6 benefits on the risk side of the equation?</p> <p>7 MS. SCHMID: Objection; form.</p> <p>8 Go ahead.</p> <p>9 A. Yes, as I mentioned earlier, that it was</p> <p>10 a less well-studied device, less-robust device in</p> <p>11 terms of its incontinence outcomes, but a minimally</p> <p>12 invasive procedure with less tunnelling, a single</p> <p>13 incision, less risk of damaging surrounding</p> <p>14 structures.</p> <p>15 MR. ZONIES: Why don't we go ahead and take</p> <p>16 a break. It's been an hour. Is that all right?</p> <p>17 MS. SCHMID: Absolutely. You were maybe</p> <p>18 reading my mind.</p> <p>19 (A recess was taken from 11:29 a.m. until</p> <p>20 11:40 a.m.)</p> <p>21 (Exhibit Number 4 was marked for</p> <p>22 identification.)</p> <p>23 Q. (By Mr. Zonies) And what else did you</p> <p>24 say you brought with you today, Doctor?</p> <p>25 A. I have my fee schedule. I have my trial</p>



<p style="text-align: right;">Page 46</p> <p>1 and testimony history. I have the notice that has</p> <p>2 already been marked as Exhibit 1, but I brought my</p> <p>3 notice. I brought e-mails of communications I've</p> <p>4 had with Johnson &amp; Johnson when I was a preceptor.</p> <p>5 I've been able to locate one contract that I had</p> <p>6 with Johnson &amp; Johnson Ethicon in 2011. I have</p> <p>7 some written communications between myself and</p> <p>8 Butler Snow. And then I have my invoice for the</p> <p>9 TVT-Secur report that I prepared. And then there</p> <p>10 was one article that I wasn't certain if it was on</p> <p>11 the reliance list or in any of the binders, so I</p> <p>12 decided to bring this article in case it's not</p> <p>13 included in my binders.</p> <p>14 Q. Okay. Could I get that stack? And</p> <p>15 we'll go ahead and get it marked.</p> <p>16 So we've marked as Exhibit 4 your updated</p> <p>17 CV. Is there anything on your updated CV, Doctor,</p> <p>18 that would be specific to TVT-S?</p> <p>19 A. You mean since the last update?</p> <p>20 Q. Yes.</p> <p>21 A. No.</p> <p>22 Q. And then this is -- we'll mark as</p> <p>23 Exhibit 5 your updated testimony list.</p> <p>24 (Exhibit Number 5 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. (By Mr. Zonies) And Exhibit 7 is your</p> <p>2 consulting agreement with Ethicon for 2011 through</p> <p>3 2012, correct?</p> <p>4 A. Correct.</p> <p>5 Q. Is that your last consulting agreement</p> <p>6 you had with Ethicon J&amp;J?</p> <p>7 A. Correct.</p> <p>8 Q. And you have testified previously that</p> <p>9 you had one of these for every year when you were</p> <p>10 consulting for Ethicon, correct?</p> <p>11 A. Correct.</p> <p>12 Q. And when did you start consulting for</p> <p>13 Ethicon?</p> <p>14 A. From the years 2004 to 2012.</p> <p>15 Q. And these -- this Exhibit 7, your</p> <p>16 consulting agreement, has in it dollar amounts that</p> <p>17 you will be paid; is that right?</p> <p>18 A. It's a contract. I think it mentions</p> <p>19 what you get paid for which particular activities</p> <p>20 that you participated in, and then it mentions what</p> <p>21 the maximum contract would be for the calendar</p> <p>22 year.</p> <p>23 Q. Right. So if you look on Exhibit 7, for</p> <p>24 example, on -- I don't know if there's a page</p> <p>25 number there, but it talks about a compensation --</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. (By Mr. Zonies) And this has as your</p> <p>2 last testimony the Perry case; is that right?</p> <p>3 That's the last time you testified?</p> <p>4 A. That's correct, yes.</p> <p>5 (Exhibit Number 6 was marked for</p> <p>6 identification.)</p> <p>7 Q. (By Mr. Zonies) And as Exhibit 6, we'll</p> <p>8 mark -- can you describe what that is, Doctor?</p> <p>9 A. That is a -- it's about ten e-mails</p> <p>10 between myself and Ethicon, because I was asked to</p> <p>11 bring communications, e-mail communications that</p> <p>12 I've had.</p> <p>13 Q. And on Exhibit 6, these e-mail</p> <p>14 communications use a Gmail e-mail address for you,</p> <p>15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. You also have communications with</p> <p>18 Ethicon using a Hotmail account, correct?</p> <p>19 A. I did, but I haven't had the Hotmail</p> <p>20 since I went to Gmail.</p> <p>21 Q. And so you don't have copies anymore of</p> <p>22 the Hotmail account?</p> <p>23 A. Correct.</p> <p>24 (Exhibit Number 7 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 49</p> <p>1 annual compensation amount of \$94,000, or</p> <p>2 something; do you see that at the bottom?</p> <p>3 A. It says, "The parties agree that the</p> <p>4 compensation paid to consultants shall not exceed</p> <p>5 \$94,500 per contract term except as may be mutually</p> <p>6 agreed in writing by the parties."</p> <p>7 Q. Okay. And each of the contracts that</p> <p>8 you had with Ethicon had some sort of a maximum</p> <p>9 compensation per annum, correct?</p> <p>10 A. Correct.</p> <p>11 Q. And, Doctor, I have -- I believe it's</p> <p>12 eight documents there from Butler Snow to you; is</p> <p>13 that right?</p> <p>14 A. Yes.</p> <p>15 Q. And could you please describe those?</p> <p>16 A. These are cover letters from Butler and</p> <p>17 Snow paralegals that are usually accompanying any</p> <p>18 kind of material that they sent me in regards to</p> <p>19 preparing a report. So the materials that were</p> <p>20 sent with this on the USB or have been submitted at</p> <p>21 other time points, but these are just cover</p> <p>22 letters.</p> <p>23 MR. ZONIES: And we'll mark that as</p> <p>24 Exhibit 8 as a group.</p> <p>25 MS. SCHMID: Retro.</p>



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<p>1 (Exhibit Number 8 was marked for 2 identification.)</p> <p>3 Q. (By Mr. Zonies) And, Doctor, Exhibit 8, 4 are these specific to TVT-S, these cover letters 5 you received from Butler Snow?</p> <p>6 A. Not necessarily. There's very little 7 detail on what was included in there, so I -- some 8 of them may have been, but they may be related to 9 other products.</p> <p>10 Q. And then we have Exhibit 9 is your -- I 11 believe your invoice for TVT-S report, is what it 12 says, correct?</p> <p>13 A. That's correct.</p> <p>14 (Exhibit Number 9 was marked for 15 identification.)</p> <p>16 Q. (By Mr. Zonies) So on Exhibit 9, 17 Doctor, it has a date. Can you tell me the 18 importance or significance of the date 19 November through December, and what the date says?</p> <p>20 A. So it says "Date: November 1 through 21 December 6," so it's just a time period. So I 22 don't know what the actual date was of when the 14 23 hours of preparation were, but it was sometime 24 between those two dates. And then it shows my 25 hourly rate for the different types of activities.</p>	<p>1 spent reviewing the scientific articles that are 2 mentioned either in the report or attached as your 3 reliance materials, correct?</p> <p>4 MS. SCHMID: Objection; form.</p> <p>5 A. Yeah, a lot of these articles I have 6 reviewed previously outside of preparation for this 7 report, so the 14 hours primarily was looking at 8 some of the larger reports, but a lot of these 9 reports and studies I've looked at previously, and 10 so certainly I didn't charge for that time.</p> <p>11 Q. (By Mr. Zonies) But for drafting your 12 TVT-S report specifically, can you tell me what -- 13 in as much detail as you can, what the 14 hours was 14 made up of?</p> <p>15 A. Okay. So the 14 hours was made up of 16 compiling my background and qualifications, an 17 overview of the spectrum of urinary incontinence, a 18 description of treatment options for urinary 19 incontinence, a discussion of the development of 20 the TVT device, starting with the TVT Classic 21 device, and then later in the report, more 22 specifically, to TVT-Secur, then a compilation of 23 my own personal experience with the device, 24 discussion of the benefits of the device, 25 discussion of the randomized controlled trials,</p>
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<p>1 The only activity was preparation of the report. 2 There was no record review of individual 3 plaintiffs. There was no -- obviously no IME for 4 this product. We didn't have any face-to-face 5 conferences or phone conferences, so it says 6 "Preparation of report, 14 hours, hourly rate \$500, 7 total charge \$7,000."</p> <p>8 Q. And is that the only invoice you've ever 9 created for TVT-S?</p> <p>10 A. Correct.</p> <p>11 Q. Between the dates of November 1st and 12 December 6th of 2015, you have 14 hours on this 13 invoice for preparation of your TVT-S report, 14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. And when you say preparation of your 17 TVT-S report, you're speaking of the report that 18 has been marked as Exhibit 3 in this deposition, 19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. And is it your testimony that the sum 22 total of time that you spent on researching and 23 drafting Exhibit 3 is 14 hours?</p> <p>24 A. Correct.</p> <p>25 Q. And that would include all the time you</p>	<p>1 discussion of polypropylene mesh characteristics, 2 discussion of potential complications or complaints 3 against the device, other claims that have been 4 made against the device, discussion of the 5 information for users, patient brochures, 6 professional education program, credentialing. And 7 then at the very end is my summary of opinions. So 8 that's what the 14 hours were about in terms of 9 preparing all of that. That includes me personally 10 typing this report, doing the editing, the 11 formatting. And I don't have a secretary or a 12 personal assistant or anybody that helped me with 13 this report. I do it myself.</p> <p>14 Q. So you reviewed some of the plaintiff's 15 experts' TVT-S reports prior to drafting this 16 report; is that correct?</p> <p>17 A. I have looked at plaintiff experts' 18 reports, maybe not specific to the TVT-Secur 19 product, but some of that overlapped with the Perry 20 case when I had been an expert on behalf of Ethicon 21 in that case. That case involved TVT-Abbrevio, but 22 a lot of the general arguments that are made 23 against polypropylene mesh from the plaintiff 24 experts I've reviewed, yes.</p> <p>25 Q. And so in your report starting at page</p>

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<p>1 21 where we were looking, there's a picture of the</p> <p>2 TVT-Secur and a description of the procedure; is</p> <p>3 that right?</p> <p>4 A. That's right.</p> <p>5 Q. And if you look at the next eight or</p> <p>6 nine pages or so, there's -- you discuss the</p> <p>7 various studies that have specifically studied the</p> <p>8 TVT-S, correct?</p> <p>9 A. That's correct.</p> <p>10 Q. Was your review and drafting of this</p> <p>11 portion of the report about the TVT-S studies,</p> <p>12 that's within the 14 hours; is that correct?</p> <p>13 A. That's correct.</p> <p>14 Q. Many of the studies you discuss in here,</p> <p>15 for example, are not studies that you would have</p> <p>16 normally seen in your practice. You specifically</p> <p>17 got those studies and read them and put them into</p> <p>18 this report; is that fair?</p> <p>19 MS. SCHMID: Objection; form.</p> <p>20 A. No, that's not correct.</p> <p>21 Q. (By Mr. Zonies) What publications do</p> <p>22 you normally subscribe to?</p> <p>23 A. Journal of Urology, Urology,</p> <p>24 International Urogynecology, International Urology</p> <p>25 and Nephrology, Neurology, and Urodynamics. Those</p>	<p>1 A. Yes.</p> <p>2 Q. Why did you bring this?</p> <p>3 A. It was an article that I had come across</p> <p>4 recently. It's an article that I reviewed with my</p> <p>5 residents. We have journal clubs, and it was an</p> <p>6 article that I thought might come up that I wanted</p> <p>7 to have in these binders, but when I prepared the</p> <p>8 reliance list, you know, we prepared that weeks</p> <p>9 ago, this is something I had read only recently, so</p> <p>10 I thought it was one that I wanted to have</p> <p>11 available to me.</p> <p>12 Q. And what did you find instructive in</p> <p>13 this article?</p> <p>14 A. I thought it was very telling how the</p> <p>15 revision rate on patients that had polypropylene</p> <p>16 mesh was quite low. Only one in 30 patients had a</p> <p>17 revision in Canada. And then they also looked to</p> <p>18 see if there were any trends or factors that they</p> <p>19 could identify on who would be more likely to have</p> <p>20 a revision.</p> <p>21 So when teaching residents and students,</p> <p>22 fellows, I try to help them understand how to use</p> <p>23 products in their practice and what risk factors</p> <p>24 they can obviate in order to lessen complications</p> <p>25 for their patients.</p>
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<p>1 are the main journals that I review for and that I</p> <p>2 read.</p> <p>3 Q. Do you subscribe to Menopause?</p> <p>4 A. Menopause, no.</p> <p>5 Q. Do you subscribe to Nature?</p> <p>6 A. I have access to Nature. Being at the</p> <p>7 university, I need a subscription for very little</p> <p>8 of these journals since the library there allows</p> <p>9 anybody who's a faculty member to have access to</p> <p>10 the journals. They have a group rate, you know,</p> <p>11 for the faculty, so I don't have to subscribe to</p> <p>12 many of these journals. The ones I mentioned are</p> <p>13 ones that I review for and I actively read, but</p> <p>14 it's different, maybe, than what a private</p> <p>15 practitioner would have.</p> <p>16 (Exhibit Number 10 was marked for</p> <p>17 identification.)</p> <p>18 Q. (By Mr. Zonies) Exhibit 10 is a</p> <p>19 scientific article that you brought with you today</p> <p>20 entitled "Removal or revision of vaginal mesh used</p> <p>21 for the treatment of stress urinary incontinence."</p> <p>22 The first author is Welk, W-e-l-k; is that right?</p> <p>23 A. That's correct.</p> <p>24 Q. And this is a 2015 publication in JAMA;</p> <p>25 is that right?</p>	<p>1 Q. And what were some of the risk factors</p> <p>2 identified in there that you discussed with some of</p> <p>3 your residents and fellows?</p> <p>4 A. Well, surprisingly, the traditional risk</p> <p>5 factors, such as diabetes, did not make a</p> <p>6 difference in outcome. It didn't reach statistical</p> <p>7 significance in terms of patients that had a</p> <p>8 complication. You would expect the diabetic to</p> <p>9 have poor wound-healing, and so you would expect</p> <p>10 them to have a higher incidence of wound-related</p> <p>11 complications, and they did not.</p> <p>12 Surgeon experience didn't matter, to some</p> <p>13 extent. Surgeon specialty did not matter. So</p> <p>14 whether you were a urologist or a gynecologist, the</p> <p>15 chance of having a complication was about the same.</p> <p>16 The type of practice setting had a small</p> <p>17 difference in terms of risk. There seemed to be</p> <p>18 less complications in the academic practice, but</p> <p>19 that's a very common bias that you see in papers</p> <p>20 that are written by academics, that academic</p> <p>21 centers -- we do more cases, and we're smarter than</p> <p>22 other people, so we get better results. So I'm</p> <p>23 always cautious about that result when it comes to</p> <p>24 an academic institution.</p> <p>25 Concomitant hysterectomy did show maybe a</p>

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<p>1 slight increase in having more complications.</p> <p>2 Also, if patients were seen frequently in the</p> <p>3 previous year, for whatever reason, they tended to</p> <p>4 have a greater risk of having a complication than</p> <p>5 patients that were seen less frequently. The way I</p> <p>6 would explain that is probably patients that are</p> <p>7 referred to experts, you know, are not seen by that</p> <p>8 expert multiple times before they operate on them.</p> <p>9 Q. Between your invoice that we went over</p> <p>10 in December, is it -- strike that.</p> <p>11 Doctor, your invoice runs from</p> <p>12 November through December of 2015 where you spent</p> <p>13 that 14 hours, correct?</p> <p>14 A. Correct.</p> <p>15 Q. Was your report completed by December of</p> <p>16 2016 in the form that we're looking at it in</p> <p>17 Exhibit 3 -- I'm sorry. Strike that.</p> <p>18 Was your report completed in its entirety in</p> <p>19 the form that we're looking at in Exhibit 3 by</p> <p>20 December of 2015?</p> <p>21 A. It was 99 percent completed.</p> <p>22 Q. Do you recall any changes you made to</p> <p>23 the report subsequent to December of 2015?</p> <p>24 A. There had maybe some typos, some</p> <p>25 grammatical errors, formatting, very minor stuff,</p>	<p>1 that document?</p> <p>2 A. Probably in the last month.</p> <p>3 Q. How did you happen to come across it, or</p> <p>4 what brought it to your attention?</p> <p>5 A. When I was asked to prepare the USB</p> <p>6 after I was served the notice of deposition in</p> <p>7 order to collect anything that I had on the device,</p> <p>8 I went through my notebook, and it was an article</p> <p>9 that I had downloaded previously in my own personal</p> <p>10 interest in TVT-Secur.</p> <p>11 TVT-Secur I've been reading about for a long</p> <p>12 time. I have more experience with this device than</p> <p>13 any of the TVT products virtually that I've done.</p> <p>14 And I taught on the device. It was a big part of</p> <p>15 my practice. So I knew a lot about this device.</p> <p>16 And I was very up to date on the medical</p> <p>17 literature, you know, contemporarily as the</p> <p>18 articles were published and became available.</p> <p>19 Even after I stopped using the device, you</p> <p>20 know, commonly, and when it was no longer</p> <p>21 available, I still was interested in how it</p> <p>22 performed.</p> <p>23 Q. Were you upset that Ethicon pulled the</p> <p>24 TVT-S off the market?</p> <p>25 A. I was disappointed, yes.</p>
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<p>1 but no changes with respect to the content.</p> <p>2 Q. With the exception of the Welk article</p> <p>3 that we were just looking at, Exhibit 10, were</p> <p>4 there any materials that you reviewed specific to</p> <p>5 TVT-S between December of 2015 and today that have</p> <p>6 informed your opinions that you're giving in this</p> <p>7 case?</p> <p>8 MS. SCHMID: Objection; form. You mean</p> <p>9 other than -- do you want him to go through the</p> <p>10 four binders?</p> <p>11 MR. ZONIES: Thank you.</p> <p>12 Q. (By Mr. Zonies) Let me put it this way:</p> <p>13 Doctor, aside from your report and the reliance</p> <p>14 materials that are attached to your report,</p> <p>15 Exhibit 3, were there any other materials that you</p> <p>16 have reviewed since December of 2015 that informed</p> <p>17 your opinion regarding the TVT-S?</p> <p>18 A. Yes. There is one other article that is</p> <p>19 on the USB, by Cornau. I'm not sure if I'm</p> <p>20 pronouncing that right. I believe the first author</p> <p>21 is C-o-r-n-a-u. It's from the European Urology</p> <p>22 Journal, which is a journal I read commonly. I</p> <p>23 should have mentioned that one. But it's a French</p> <p>24 study looking at midterm results with TVT-Secur.</p> <p>25 Q. And when do you believe you reviewed</p>	<p>1 Q. Did you use it right up until the time</p> <p>2 that it was pulled from the market?</p> <p>3 MS. SCHMID: Objection; form.</p> <p>4 A. Well, as I mentioned earlier, you know,</p> <p>5 the dates that I used it commonly when I</p> <p>6 transitioned to TVT-Abbrevio, I still used the Secur</p> <p>7 occasionally, but not as often. And that's what I</p> <p>8 did up until the time it was no longer being</p> <p>9 offered.</p> <p>10 Q. And when it was pulled off the market,</p> <p>11 did you actually have to return the TVT-Securs that</p> <p>12 you had? Or did you get a chance to implant those</p> <p>13 after you were told that it was no longer going to</p> <p>14 be offered?</p> <p>15 A. When I transitioned to TVT-Abbrevio, that</p> <p>16 was what I was doing primarily, and that's what the</p> <p>17 hospital would have on the shelf for me. Products</p> <p>18 that I used less commonly, we would just order them</p> <p>19 on a case-by-case basis, so that way we didn't have</p> <p>20 too much inventory.</p> <p>21 The hospitals are very careful about not</p> <p>22 having too much inventory, and so they go to the</p> <p>23 surgeons and say, "What are you using commonly, you</p> <p>24 know, and what should we be stocking for you?" And</p> <p>25 so products that you didn't use commonly, then you</p>

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<p>1 wouldn't have them on the shelf.</p> <p>2 So the answer is no, we didn't have to hurry</p> <p>3 up and use them up or send anything back. You</p> <p>4 couldn't send the device back. It was never</p> <p>5 recalled. So if a product's no longer being</p> <p>6 offered, that's very different than recall.</p> <p>7 In a recall, the device would be sent back.</p> <p>8 TVT-Secur was never recalled.</p> <p>9 Q. When TVT-Secur was no longer being</p> <p>10 offered, did you implant TVT-Securs after you were</p> <p>11 informed it was no longer being offered?</p> <p>12 A. I don't believe so.</p> <p>13 Q. The Cornau article that you're</p> <p>14 discussing, that demonstrates that there's a very</p> <p>15 precipitous fall-off in efficacy over time with the</p> <p>16 TVT-Secur; is that correct?</p> <p>17 MS. SCHMID: Objection; form.</p> <p>18 A. It showed that the midterm results</p> <p>19 weren't as good as the short-term results. How</p> <p>20 that happened or at what time point that happened,</p> <p>21 I'd have to go back and look at the article again.</p> <p>22 Q. (By Mr. Zonies) And is it your</p> <p>23 testimony that you had reviewed the Cornau article</p> <p>24 before you wrote your report, but simply forgot to</p> <p>25 include it on the reliance? Or did you review the</p>	<p>1 MS. SCHMID: Objection; form.</p> <p>2 A. I would say there's a very small</p> <p>3 difference in the efficacy, maybe 5 percentage</p> <p>4 points. So I think it was -- it had a very good</p> <p>5 short-term efficacy, certainly in my hands it did,</p> <p>6 and my study. It was performing almost as well as</p> <p>7 the results I was getting with full-length slings.</p> <p>8 I believe I recorded 85 percent success in my</p> <p>9 short-term study, so that was not very different</p> <p>10 than what I was getting with full-length slings.</p> <p>11 Q. Well, you actually reported 82 percent,</p> <p>12 didn't you?</p> <p>13 A. Excuse me. 82 percent.</p> <p>14 Q. And with your TVT and TVT-O, you</p> <p>15 actually have reported 85 to 90 percent, correct?</p> <p>16 A. I would have to look at what you're</p> <p>17 quoting. I have had a previous abstract on TVT-O.</p> <p>18 I don't believe I've ever had an abstract on TVT</p> <p>19 full or retropubic TVT.</p> <p>20 Q. So my question, Doctor, is, you would</p> <p>21 agree that, even in your hands, that the TVT-Secur</p> <p>22 in short-term results did not perform as well as</p> <p>23 the TVT and TVT-O, correct?</p> <p>24 MS. SCHMID: Objection; form.</p> <p>25 A. I wouldn't agree with that.</p>
Page 63	Page 65
<p>1 Cornau article after you wrote your report?</p> <p>2 A. I had read it years ago, probably when</p> <p>3 it became available, but I didn't read it in</p> <p>4 preparation of my report. It wasn't an article</p> <p>5 that I was relying on at the time.</p> <p>6 Q. It wasn't an article that you relied on</p> <p>7 in your report, correct?</p> <p>8 A. Correct.</p> <p>9 Q. It wasn't -- the Cornau article is an</p> <p>10 article that shows that the TVT-Secur loses</p> <p>11 efficacy over time, correct?</p> <p>12 MS. SCHMID: Objection; form, argumentative.</p> <p>13 A. It showed that the midterm results were</p> <p>14 not as good as the short-term results. But there's</p> <p>15 other articles in my report that I quote that show</p> <p>16 inferior results with TVT-Secur maybe compared to</p> <p>17 full-length slings, so that was just one article.</p> <p>18 There's other articles that show, you know, less</p> <p>19 results in the midterm than the short-term that</p> <p>20 I've quoted. So I think there's other articles</p> <p>21 that represent that outcome.</p> <p>22 Q. (By Mr. Zonies) Yeah. And if I</p> <p>23 understand correctly, first of all, you would agree</p> <p>24 that the TVT-Secur, even in the short-term, was not</p> <p>25 as efficacious as the TVT or the TVT-O, correct?</p>	<p>1 Q. (By Mr. Zonies) The 5 percent</p> <p>2 difference, you just don't think that that matters,</p> <p>3 the 5 percent difference?</p> <p>4 A. I think you would have to do a</p> <p>5 head-to-head trial between the Secur and the</p> <p>6 Obturator and do that prospectively and</p> <p>7 consecutively to really be confident, because</p> <p>8 there's a lot of other factors that go into that.</p> <p>9 Q. So you would look for a randomized</p> <p>10 control trial comparing TVT-Secur to TVT-O, for</p> <p>11 example, correct?</p> <p>12 MS. SCHMID: Had you finished your prior</p> <p>13 response, Dr. Flynn?</p> <p>14 THE WITNESS: No, I didn't.</p> <p>15 MS. SCHMID: Okay. Why don't you go ahead</p> <p>16 and finish your prior response.</p> <p>17 Q. (By Mr. Zonies) I'm sorry. I didn't</p> <p>18 mean to cut you off, Doctor.</p> <p>19 A. That's okay. What I was going to finish</p> <p>20 saying was that as I had been in practice for</p> <p>21 longer and this continues to happen in my practice,</p> <p>22 I tend to see more and more complex patients. My</p> <p>23 practice initially was that of what we'd call</p> <p>24 primary incontinence where you would see what the</p> <p>25 AUA would describe as index cases, and then over</p>

<p style="text-align: right;">Page 66</p> <p>1 time, the practice became more tertiary, which is</p> <p>2 something you'd expect at a tertiary institution</p> <p>3 and academic teaching center.</p> <p>4 So when I was doing TVT-Secur, I was</p> <p>5 already, you know, four or five years into</p> <p>6 practice, and so I was starting to see more and</p> <p>7 more difficult patients. So the only way to really</p> <p>8 correct for that is doing the cases consecutively.</p> <p>9 Do one TVT-Secur, then the next patient that you</p> <p>10 see, do the TVT Obturator, and then collect the</p> <p>11 results.</p> <p>12 So if you're comparing nonconsecutive</p> <p>13 series, even within the same surgeon's hands,</p> <p>14 there's potentially some differences in the cohort.</p> <p>15 Also, when you compare studies across the</p> <p>16 literature, you can see something similar.</p> <p>17 In order to correct for that, people would</p> <p>18 then try to put together a systematic review, or</p> <p>19 meta-analysis, which is the highest level of data,</p> <p>20 and then look at what the meta-analysis of the</p> <p>21 systematic reviews show in order to see the true</p> <p>22 differences between the products.</p> <p>23 Q. Okay. So a couple of questions.</p> <p>24 Is it your testimony that a meta-analysis is</p> <p>25 the highest level of data? Yes or no?</p>	<p style="text-align: right;">Page 68</p> <p>1 has to be enough studies to make the systematic</p> <p>2 review and meta-analysis valuable, so if there's</p> <p>3 four or five studies that have been published to</p> <p>4 date, the meta-analysis and systematic review is</p> <p>5 not going to be very accurate. The more studies</p> <p>6 that are collected, the greater degree of accuracy</p> <p>7 that the meta-analysis or systematic review are</p> <p>8 capable of.</p> <p>9 Q. (By Mr. Zonies) Is it important,</p> <p>10 Doctor, that the studies included within the</p> <p>11 systematic review and/or meta-analysis be</p> <p>12 randomized controlled clinical trials?</p> <p>13 A. No. That's the beauty of the systematic</p> <p>14 review and the meta-analysis, is that it can</p> <p>15 correct for that to some extent.</p> <p>16 Q. In your report, Doctor, on page 22, you</p> <p>17 discuss a Cochrane review of midurethral slings; do</p> <p>18 you see that in the middle of the page 22,</p> <p>19 Exhibit 3?</p> <p>20 A. Starting with "In 2015, a Cochrane</p> <p>21 review"?</p> <p>22 Q. Yes.</p> <p>23 A. Yes.</p> <p>24 Q. The Cochrane review that you're</p> <p>25 discussing there, which is the -- cited as the Ford</p>
<p style="text-align: right;">Page 67</p> <p>1 MS. SCHMID: Objection; form.</p> <p>2 Go ahead.</p> <p>3 A. It's one of the things. There's others</p> <p>4 that have the same level of evidence, so there's a</p> <p>5 tie, you know, up there at the top.</p> <p>6 Q. (By Mr. Zonies) And a tie between a</p> <p>7 meta-analysis and what?</p> <p>8 A. A systematic review. Those are</p> <p>9 different.</p> <p>10 Q. And is it your belief that at the top of</p> <p>11 the evidence pyramid, the best evidence one can get</p> <p>12 on any scientific question about TVT slings is a</p> <p>13 systematic review or a meta-analysis?</p> <p>14 MS. SCHMID: I'm sorry. Madam Court</p> <p>15 Reporter, can you just read that back to me?</p> <p>16 MR. ZONIES: I'll ask it again.</p> <p>17 MS. SCHMID: Okay. Thank you.</p> <p>18 Q. (By Mr. Zonies) Is it your testimony,</p> <p>19 Doctor, that at the top of the evidence pyramid,</p> <p>20 the best evidence one can get on any scientific</p> <p>21 question about the TVT slings is a systematic</p> <p>22 review or a meta-analysis?</p> <p>23 MS. SCHMID: Objection; form.</p> <p>24 Go ahead.</p> <p>25 A. I would say for the most part. There</p>	<p style="text-align: right;">Page 69</p> <p>1 paper in 2015, you believe that to be the highest</p> <p>2 level of evidence because it's a systematic review,</p> <p>3 correct?</p> <p>4 MS. SCHMID: Objection; form.</p> <p>5 A. I think the Cochrane reviews, systematic</p> <p>6 reviews are very powerful, so it's level-one</p> <p>7 evidence, yes.</p> <p>8 Q. (By Mr. Zonies) And it says, "While</p> <p>9 not" -- you say in your report, "While not</p> <p>10 specifically applicable to single-incision slings</p> <p>11 like the TVT-Secur," and you go on to discuss how</p> <p>12 it's actually talking about multi-incision slings,</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. My question, Doctor, is, in your</p> <p>16 TVT-Secur report, why didn't you cite to the</p> <p>17 Cochrane review done in 2015 on single-incision</p> <p>18 slings?</p> <p>19 A. I would have to see which review you're</p> <p>20 talking about.</p> <p>21 Q. Actually, Doctor, it's the 2014 review</p> <p>22 by Nambiar, N-a-m-b-i-a-r, entitled "Single</p> <p>23 incision sling operations for urinary incontinence</p> <p>24 in women," a review. Have you ever reviewed that</p> <p>25 paper?</p>



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<p>1 A. I would have to look at it to be</p> <p>2 confident one way or the other.</p> <p>3 (Exhibit Number 11 was marked for</p> <p>4 identification.)</p> <p>5 Q. (By Mr. Zonies) Doctor, I'm handing you</p> <p>6 Exhibit 11. Have you got that in front of you?</p> <p>7 A. I do.</p> <p>8 Q. Have you ever seen this Cochrane</p> <p>9 collaboration paper entitled "Single incision sling</p> <p>10 operations for urinary incontinence in women"?</p> <p>11 A. I don't believe so.</p> <p>12 Q. And the first author is Nambiar,</p> <p>13 N-a-m-b-i-a-r; is that right?</p> <p>14 A. Correct.</p> <p>15 Q. Doctor, this is a 2014 Cochrane review</p> <p>16 on single-incision slings. You would agree that</p> <p>17 the TVT-Secur is a single-incision sling, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And the paper you cited to is discussing</p> <p>20 multi-incision slings, correct?</p> <p>21 A. The Cochrane review from 2015?</p> <p>22 Q. Yes.</p> <p>23 A. Yes.</p> <p>24 Q. And you would agree that when analyzing</p> <p>25 the question of single-incision slings and their</p>	<p>1 Q. Right where you are, page 1, in the</p> <p>2 abstract.</p> <p>3 A. Okay.</p> <p>4 Q. "Background," the second paragraph, "It</p> <p>5 should be noted," do you see that?</p> <p>6 A. I do.</p> <p>7 Q. "It should be noted that TVT-Secur is</p> <p>8 one type of single-incision sling. It has been</p> <p>9 withdrawn from the market because of poor results."</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. And this -- the next page discusses the</p> <p>13 main results; do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. If you look at the fourth paragraph</p> <p>16 down, it starts with "Women were"; do you see that</p> <p>17 paragraph?</p> <p>18 A. I do.</p> <p>19 Q. "Women were more likely to remain</p> <p>20 incontinent after surgery with single-incision</p> <p>21 slings than with retropubic slings, such as</p> <p>22 tension-free vaginal tape (TVT) with a risk ratio</p> <p>23 of more than two"; is that right?</p> <p>24 A. Correct.</p> <p>25 Q. Do you agree with that?</p>
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<p>1 safety and efficacy, it would be much more reliable</p> <p>2 to review the Cochrane paper on single-incision</p> <p>3 slings than the Cochrane paper on multi-incision</p> <p>4 slings, correct?</p> <p>5 A. No, I wouldn't agree to that.</p> <p>6 Q. You think that the paper on</p> <p>7 multi-incision slings is more informative than the</p> <p>8 paper on single-incision slings when looking at the</p> <p>9 safety and efficacy of a single-incision sling?</p> <p>10 A. I think they're both important studies.</p> <p>11 I'm not going to value one over the other.</p> <p>12 Q. If you take a look at the Nambiar,</p> <p>13 Doctor, the Cochrane review from 2014, and you look</p> <p>14 at page 1 --</p> <p>15 MS. SCHMID: Are you on Exhibit 11 right</p> <p>16 now, right?</p> <p>17 MR. ZONIES: Yes.</p> <p>18 Q. (By Mr. Zonies) And you actually have</p> <p>19 it open, I think, to page 1, the abstract; do you</p> <p>20 see that?</p> <p>21 A. Yeah.</p> <p>22 Q. And the abstract says, "It should be</p> <p>23 noted" -- I'm sorry, in the "Background" section,</p> <p>24 second paragraph, do you have that?</p> <p>25 A. Which page?</p>	<p>1 MS. SCHMID: Objection; foundation.</p> <p>2 A. I would agree with part of it.</p> <p>3 Q. (By Mr. Zonies) Which part?</p> <p>4 A. The statement that says "more likely to</p> <p>5 remain incontinent." I would characterize it as</p> <p>6 more likely to have recurrent incontinence. But</p> <p>7 the risk ratio, that seems to be quite high to me.</p> <p>8 I -- at least in my own personal experience, it</p> <p>9 wouldn't be 2.08.</p> <p>10 Q. And, Doctor, just to be clear, your</p> <p>11 report -- your expert report in this case, is it</p> <p>12 based solely on your personal experience? Or did</p> <p>13 you actually review scientific studies on these</p> <p>14 issues?</p> <p>15 A. It's based on both.</p> <p>16 Q. And so you've testified that the</p> <p>17 Cochrane reviews, systematic reviews are level-one</p> <p>18 evidence, in your opinion, correct?</p> <p>19 A. Correct.</p> <p>20 Q. And would you agree with this level-one</p> <p>21 evidence that there is, as it says in the next</p> <p>22 sentence, "a higher risk of de novo urgency" with</p> <p>23 single-incision slings such as the TVT-Secur?</p> <p>24 MS. SCHMID: Sorry, where were you reading</p> <p>25 that from?</p>



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<p>1 MR. ZONIES: The next sentence, "Duration of</p> <p>2 the operation was slightly shorter for</p> <p>3 single-incision slings but with higher risk of de</p> <p>4 novo urgency," again, more than a two-time relative</p> <p>5 risk.</p> <p>6 Q. (By Mr. Zonies) Do you agree or</p> <p>7 disagree with that statement?</p> <p>8 MS. SCHMID: Objection; foundation.</p> <p>9 A. I'm not sure if that relative risk is</p> <p>10 talking about shorter operation or higher risk of</p> <p>11 de novo urgency. It's a little bit confusing to me</p> <p>12 the way that was written.</p> <p>13 Q. (By Mr. Zonies) Do you agree that</p> <p>14 there's a higher risk of de novo urgency with the</p> <p>15 TVT-Secur than the TVT retropubic?</p> <p>16 MS. SCHMID: Objection; form, vague.</p> <p>17 A. I've never seen that reported. I don't</p> <p>18 remember reading that in any other review or my own</p> <p>19 personal experience with the device.</p> <p>20 Q. (By Mr. Zonies) You've never read that</p> <p>21 in any of the papers that you reviewed?</p> <p>22 A. I would have to go back and look at all</p> <p>23 of them, but that stands out, to me, as being</p> <p>24 something that I'm surprised to hear. I don't --</p> <p>25 that's not what most physicians would believe.</p>	<p>1 Do you agree or disagree with that</p> <p>2 statement?</p> <p>3 MS. SCHMID: Objection; form, foundation.</p> <p>4 A. I disagree with that statement.</p> <p>5 Q. (By Mr. Zonies) You disagree with this</p> <p>6 Cochrane collaboration in a number of ways, don't</p> <p>7 you, Doctor?</p> <p>8 A. I disagree with some of the conclusions.</p> <p>9 I think there's other systematic reviews, for</p> <p>10 instance, Walsh or Tomaselli, Tincello, Tang.</p> <p>11 There's other reports that say something very</p> <p>12 different, that report, the procedure being less</p> <p>13 invasive and having similar outcomes and similar</p> <p>14 risk profile.</p> <p>15 Q. Well, Doctor, you chose to cite on page</p> <p>16 22 of your report -- and, in fact, it's the first</p> <p>17 scientific article you cite in your report, in this</p> <p>18 section of your report, you chose to cite to the</p> <p>19 Cochrane review, but the Cochrane was looking at</p> <p>20 TVT and TVT-O, right? You chose that?</p> <p>21 A. I had --</p> <p>22 MS. SCHMID: Let me object to the form.</p> <p>23 Misstatement. Also, I mean -- just be careful --</p> <p>24 just be careful, because the reliance --</p> <p>25 MR. ZONIES: I'm being careful.</p>
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<p>1 Q. Well, you certainly don't believe it,</p> <p>2 right?</p> <p>3 A. I have a tough time believing that. I</p> <p>4 would have to go back and look at that and other</p> <p>5 papers, but I'm surprised to hear that.</p> <p>6 Q. And the next paragraph discusses a</p> <p>7 comparison of the TVT-Secur to the TVT Obturator,</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. And it says in that paragraph that the</p> <p>11 single-incision slings resulted in higher</p> <p>12 incontinence rates compared to the obturator sling,</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. Do you agree or disagree with that?</p> <p>16 MS. SCHMID: Objection; form, foundation.</p> <p>17 A. I could agree with that. I think I</p> <p>18 mentioned earlier that the full-length slings were</p> <p>19 a more robust procedure, in my opinion.</p> <p>20 Q. (By Mr. Zonies) And then it goes on to</p> <p>21 say, "The adverse event profile was significantly</p> <p>22 worse, specifically consisting of higher risks of</p> <p>23 vaginal mesh exposure, bladder/urethral erosion and</p> <p>24 operative blood loss" with the TVT-Secur as</p> <p>25 compared to the obturator.</p>	<p>1 MS. SCHMID: -- does, in fact, include</p> <p>2 Exhibit Number 11.</p> <p>3 MR. ZONIES: Do you want to go under oath</p> <p>4 now or are you going to keep doing that? Do not do</p> <p>5 that during my deposition, please.</p> <p>6 MS. SCHMID: Keep doing what?</p> <p>7 MR. ZONIES: Do not coach your witness</p> <p>8 during my deposition. If you want to ask him</p> <p>9 questions later, you're more than welcome to.</p> <p>10 MS. SCHMID: Okay.</p> <p>11 A. What I'd like to go on the record is I</p> <p>12 misspoke earlier that this article that you</p> <p>13 presented to me is, in fact, on the reliance list.</p> <p>14 I looked at the reliance list quickly. There's</p> <p>15 over 200 articles on this list. I'm sorry if I</p> <p>16 don't remember every single article on the list,</p> <p>17 but this Nambiar article is on my reliance list.</p> <p>18 Q. (By Mr. Zonies) So my question, then,</p> <p>19 Doctor, is why, on page 22 of your report, am I not</p> <p>20 reading about the Nambiar article? Instead, you've</p> <p>21 chosen to discuss the Ford article that has nothing</p> <p>22 to do with this device.</p> <p>23 MS. SCHMID: Objection; form, argumentative.</p> <p>24 A. If you look at the way this report is</p> <p>25 prepared, it walks you through the history of TVT.</p>

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<p>1 And so there's a transition point. Up until page</p> <p>2 22, the majority of what is in the report is about</p> <p>3 the history of incontinence and the TVT device.</p> <p>4 And then as we go further in the report, starting</p> <p>5 on page 23, that's when we start to specifically</p> <p>6 talk about TVT-Secur.</p> <p>7 Q. (By Mr. Zonies) Doctor, did you choose</p> <p>8 not to mention this Cochrane review because you</p> <p>9 didn't read it before, as you earlier testified, or</p> <p>10 because you didn't like what it said?</p> <p>11 MS. SCHMID: Objection; argumentative.</p> <p>12 Go ahead.</p> <p>13 A. Of the articles on my reliance list, I</p> <p>14 haven't read all of those as comprehensively as</p> <p>15 others, so there are some articles that I'm more</p> <p>16 familiar with that I've relied on for many years.</p> <p>17 And so I chose articles in my report that I'm more</p> <p>18 familiar with. I think that that's what any expert</p> <p>19 would do. The articles that you're most familiar</p> <p>20 with that you have the greatest degree of</p> <p>21 confidence in that are similar to your own personal</p> <p>22 experience with the device, those are the ones you</p> <p>23 tend to cite and talk about.</p> <p>24 Q. So Doctor, I want to be sure we get this</p> <p>25 right.</p>	<p>1 in 2011 is another systematic review and</p> <p>2 meta-analysis of over a thousand patients that had</p> <p>3 a mesh exposure rate of 2.4. Tomaselli, 2013, RCT.</p> <p>4 RCTs are a very high level of evidence as well, and</p> <p>5 didn't show a high exposure rate any different than</p> <p>6 TVT-O.</p> <p>7 So you have to look at a number of studies.</p> <p>8 I think there's always going to be one study, even</p> <p>9 possibly a systematic review that might report</p> <p>10 something different than other systematic reviews.</p> <p>11 So there's multiple systematic reviews on mini</p> <p>12 slings. I chose to cite the Wall study, and that's</p> <p>13 what I have in my report. So I did choose one of</p> <p>14 the systematic reviews. It was one that was -- one</p> <p>15 that I was more familiar with.</p> <p>16 Q. (By Mr. Zonies) And it was the one that</p> <p>17 supports your opinion, not the one that is contrary</p> <p>18 to your opinion, correct?</p> <p>19 MS. SCHMID: Objection; form, argumentative.</p> <p>20 Go ahead.</p> <p>21 A. It supports my experience and my</p> <p>22 opinions in regards to TVT-Secur.</p> <p>23 Q. (By Mr. Zonies) You picked the one that</p> <p>24 supports your opinions, not this one that we're</p> <p>25 looking at that is clearly contrary to your</p>
Page 79	Page 81
<p>1 You earlier testified that systematic</p> <p>2 review, to you, is the top level of evidence</p> <p>3 available on a scientific question, correct?</p> <p>4 MS. SCHMID: Objection; form, misstates</p> <p>5 testimony.</p> <p>6 Go ahead.</p> <p>7 A. That's incorrect.</p> <p>8 Q. (By Mr. Zonies) That a systematic</p> <p>9 review and/or a meta-analysis are, for you, the top</p> <p>10 level of evidence on a scientific question,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. And this Cochrane review that we're</p> <p>14 looking at now from 2014 concerning single-incision</p> <p>15 slings is, indeed, a systematic review, correct?</p> <p>16 A. Correct.</p> <p>17 Q. So in your mind, this would be the top</p> <p>18 level of evidence to look at to determine the</p> <p>19 scientific question of the safety and efficacy of a</p> <p>20 single-incision sling like TVT-Secur, correct?</p> <p>21 MS. SCHMID: Objection; form.</p> <p>22 A. This and other systematic reviews. It's</p> <p>23 not the only systematic review on TVT-Secur. And</p> <p>24 this systematic review is on mini slings. It's not</p> <p>25 just on TVT-Secur. So for instance, the Wall study</p>	<p>1 opinions, correct?</p> <p>2 MS. SCHMID: Objection; form, argumentative,</p> <p>3 misstates the document.</p> <p>4 A. I chose the one that I think most</p> <p>5 represents TVT-Secur.</p> <p>6 Q. (By Mr. Zonies) So one of the concerns</p> <p>7 that you just raised is that this is about mini</p> <p>8 slings, but you see the author's conclusions,</p> <p>9 Doctor, where it says, "TVT-Secur is inferior to</p> <p>10 standard midurethral slings for the treatment of</p> <p>11 women with stress incontinence and has already been</p> <p>12 withdrawn from clinical use"; did I read that</p> <p>13 correctly?</p> <p>14 A. You read it correctly, but the</p> <p>15 statement's incorrect.</p> <p>16 Q. And two paragraphs above that, "Overall</p> <p>17 results show the TVT-Secur is considerably inferior</p> <p>18 to retropubic and inside-out transobturator</p> <p>19 slings"; do you agree or disagree with that</p> <p>20 statement?</p> <p>21 MS. SCHMID: I'm going to object to form.</p> <p>22 It's an incomplete recitation of the sentence.</p> <p>23 A. Can I read the rest of the sentence?</p> <p>24 Q. (By Mr. Zonies) Sure.</p> <p>25 A. Okay. "But additional evidence is</p>

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<p>1 required to allow any reasonable comparison of</p> <p>2 other single-incision slings versus transobturator</p> <p>3 slings."</p> <p>4 What this report says to me is that the mini</p> <p>5 slings are inferior to the full-length retropubic</p> <p>6 and transobturator slings. And I think that's</p> <p>7 something we've stated multiple times already in</p> <p>8 this deposition, that the full-length slings, I've</p> <p>9 said earlier, are a more robust procedure with</p> <p>10 better incontinence outcomes.</p> <p>11 The mini slings have a more attractive</p> <p>12 convalescence and recovery for the patient, in my</p> <p>13 hands, less complications, so it gets back to the</p> <p>14 risks-and-benefit discussion you have with your</p> <p>15 patients.</p> <p>16 MR. ZONIES: Move to strike as</p> <p>17 nonresponsive.</p> <p>18 Q. (By Mr. Zonies) Doctor, do you see in</p> <p>19 the paragraph discussing the comparison to</p> <p>20 transobturator slings, do you see that paragraph?</p> <p>21 We were looking at that earlier. It starts with</p> <p>22 "Single-incision slings resulted in a higher</p> <p>23 incontinence rate compared with inside-out</p> <p>24 transobturator slings."</p> <p>25 A. Yes.</p>	<p>1 Q. And this is a paper you either didn't</p> <p>2 see or you certainly didn't discuss in your report,</p> <p>3 correct?</p> <p>4 A. It's listed on my reliance list, but</p> <p>5 it's not specifically discussed in the report.</p> <p>6 Q. Now, you said that randomized control</p> <p>7 trials are also good evidence; is that right?</p> <p>8 A. That's correct.</p> <p>9 Q. I'm going to hand you what's being</p> <p>10 marked as Exhibit 12.</p> <p>11 (Exhibit Number 12 was marked for</p> <p>12 identification.)</p> <p>13 Q. (By Mr. Zonies) I'm handing you what's</p> <p>14 been marked as Exhibit 12, a study by Hota,</p> <p>15 H-o-t-a, at the Harvard Medical Center. Have you</p> <p>16 ever seen that study before?</p> <p>17 A. Yes, I've seen this before.</p> <p>18 Q. You do not discuss this study in the</p> <p>19 body of your report, Doctor. I was wondering if</p> <p>20 there's a reason for that.</p> <p>21 A. The report's 50 pages long. The</p> <p>22 majority of articles listed on the reliance list</p> <p>23 are not specifically discussed in the report. When</p> <p>24 preparing the report, I selected the articles that</p> <p>25 I thought were most representative of TVT-Secur and</p>
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<p>1 Q. All right. In that paragraph, it says:</p> <p>2 The adverse event profile was significantly worse,</p> <p>3 specifically consisting of higher risks of vaginal</p> <p>4 mesh exposure with a 3.75 relative risk,</p> <p>5 bladder/urethral erosion with a 17.79 statistically</p> <p>6 significant relative risk, and operative blood</p> <p>7 loss, 18.79 statistically significant relative</p> <p>8 risk.</p> <p>9 That's what that states, correct?</p> <p>10 MS. SCHMID: Objection; form, incomplete.</p> <p>11 Go ahead.</p> <p>12 A. There's a lot there. I think we've read</p> <p>13 that paragraph a few times. This systematic review</p> <p>14 is very different than what other systematic</p> <p>15 reviews report.</p> <p>16 Q. (By Mr. Zonies) And the last sentence</p> <p>17 says, "Most of these findings were derived from the</p> <p>18 trials involving TVT-Secur. Excluding the other</p> <p>19 trials showed that the high risk of incontinence</p> <p>20 was principally associated with the use of this</p> <p>21 device. It has been withdrawn from clinical use."</p> <p>22 That's what that says, right?</p> <p>23 A. That's what it says, but it was never</p> <p>24 withdrawn. It was no longer offered. Those are</p> <p>25 very different.</p>	<p>1 the outcomes that I've experienced with my</p> <p>2 patients.</p> <p>3 Q. You selected the articles that are most</p> <p>4 consistent with your belief of the safety and</p> <p>5 efficacy of the TVT-S, correct?</p> <p>6 MS. SCHMID: Objection; form, misstates</p> <p>7 testimony.</p> <p>8 A. That's not what I said, so no, that's</p> <p>9 not correct.</p> <p>10 Q. (By Mr. Zonies) You'll see that this</p> <p>11 Hota study comes out of Harvard. It's a randomized</p> <p>12 control trial that had to be stopped because they</p> <p>13 found that the TVT-Secur was not efficacious and</p> <p>14 too risky as compared to the Obturator --</p> <p>15 MS. SCHMID: Objection; form --</p> <p>16 Q. (By Mr. Zonies) -- is that right?</p> <p>17 MS. SCHMID: I'm so sorry.</p> <p>18 MR. ZONIES: That's all right.</p> <p>19 MS. SCHMID: Objection; form, foundation,</p> <p>20 argumentative.</p> <p>21 A. I would need a little bit more time to</p> <p>22 look at the study. I'll just read the conclusion.</p> <p>23 It says, "The TVT-S seems to have a higher risk of</p> <p>24 positive postoperative cough stress test result,"</p> <p>25 meaning incontinence, "however, the procedure</p>

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<p>1 resulted in similar improvements in quality of</p> <p>2 life." I'm not seeing where it had to be stopped.</p> <p>3 I could go on and spend time reading the whole</p> <p>4 paper.</p> <p>5 Q. (By Mr. Zonies) I'll just help you,</p> <p>6 Doctor. If you turn to the next page, under</p> <p>7 "Results," the first sentence, "The study was</p> <p>8 terminated early because of the interim analysis</p> <p>9 results"; do you see that?</p> <p>10 A. I do.</p> <p>11 Q. And the last paragraph on the column</p> <p>12 next to that begins with, "An interim analysis"; do</p> <p>13 you see that, the last paragraph in the left-hand</p> <p>14 column?</p> <p>15 A. On which page?</p> <p>16 MS. SCHMID: Where are you?</p> <p>17 Q. (By Mr. Zonies) Same page, just right</p> <p>18 here (indicating).</p> <p>19 A. Okay.</p> <p>20 Q. It says, "An interim analysis was not</p> <p>21 initially planned as part of the study; however,</p> <p>22 several investigators voiced concerns about noting</p> <p>23 an increasing number of positive postoperative</p> <p>24 CTSs" -- that's a cough stress test, correct?</p> <p>25 A. Correct.</p>	<p>1 EXAMINATION</p> <p>2 BY MS. SCHMID:</p> <p>3 Q. Dr. Flynn, you were asked a number of</p> <p>4 questions about an article with the author of</p> <p>5 Cornau or Cornau; is that correct?</p> <p>6 A. That's correct.</p> <p>7 Q. And if I could just refer you to page 34</p> <p>8 of your expert report in this case, Dr. Flynn, did</p> <p>9 you, in fact, discuss and cite to the Cornau</p> <p>10 article in your expert report?</p> <p>11 A. I did.</p> <p>12 Q. All right. Earlier today in some</p> <p>13 questions from Plaintiff's counsel, you stated that</p> <p>14 continence outcomes from the TVT-Secur were</p> <p>15 "inferior"; do you recall that testimony?</p> <p>16 A. I do.</p> <p>17 Q. And what did you mean by that?</p> <p>18 MR. ZONIES: Object to the form.</p> <p>19 A. I meant that I truly believe that the</p> <p>20 full-length slings have better continence outcomes</p> <p>21 than the mini slings. It's not to say that the</p> <p>22 mini slings are not effective. They have reports</p> <p>23 of efficacy in the low 80s in many studies,</p> <p>24 including systematic reviews, and in my own</p> <p>25 experience. As it was pointed out, that the</p>
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<p>1 Q. -- "in women who had undergone a TVT-S,"</p> <p>2 and that's why the study was stopped.</p> <p>3 A. Okay.</p> <p>4 Q. You don't discuss this paper in your</p> <p>5 expert report from Harvard, correct?</p> <p>6 A. That's correct.</p> <p>7 Q. That's not the only -- you actually do</p> <p>8 discuss the Hamer, H-a-m-e-r, paper -- well, strike</p> <p>9 that.</p> <p>10 MR. ZONIES: Could we take a break for a</p> <p>11 second?</p> <p>12 MS. SCHMID: Absolutely.</p> <p>13 MR. ZONIES: How much time do we have left?</p> <p>14 What do you have, five minutes?</p> <p>15 MS. COVINGTON: Three.</p> <p>16 (A recess was taken from 12:37 p.m. until</p> <p>17 12:41 p.m.)</p> <p>18 MR. ZONIES: That's all the questions I have</p> <p>19 for now. I'll reserve my three minutes for any</p> <p>20 rebuttal questions.</p> <p>21 And also, to the extent that any of these</p> <p>22 new documents that the Doctor brought with him</p> <p>23 today present information we need to talk to him</p> <p>24 about, I'll reserve my right to ask for some more</p> <p>25 time on that. I don't expect to, but . . .</p>	<p>1 full-length slings tend to report outcomes in the</p> <p>2 high 80s even into the 90s, so there's a slight</p> <p>3 difference there that's balanced against the</p> <p>4 decreased morbidity of the TVT-Secur procedure.</p> <p>5 So I think these are all good procedures,</p> <p>6 the full-length slings and the mini slings. And</p> <p>7 it's nice having options as a surgeon. There are</p> <p>8 certain patients that you would prefer to do a less</p> <p>9 invasive procedure on. That's why I mentioned</p> <p>10 earlier that it would have been nice if TVT-Secur</p> <p>11 was still on the market, because that was a viable</p> <p>12 option in my practice, and in many people's</p> <p>13 practices. It was a commonly performed procedure.</p> <p>14 Did it perform as well as the full-length slings</p> <p>15 over time? The answer is no, but you can say that</p> <p>16 about a lot of incontinence procedures, like the</p> <p>17 Burch procedure, for instance. That tends to fail</p> <p>18 over time. The pubovaginal sling with autologous</p> <p>19 fascia, that can degrade and fail over time. If</p> <p>20 you look at the study by Michael Albo, he reported</p> <p>21 long-term success rates with Burch and pubovaginal</p> <p>22 sling to be both less than 50 percent.</p> <p>23 And so there's plenty of evidence in the</p> <p>24 medical literature to show that incontinence is a</p> <p>25 degenerative condition and that outcomes can</p>

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<p>1 decrease over time. And so TVT-Secur is no</p> <p>2 different, really, than any other incontinence</p> <p>3 procedure that has been reported to date.</p> <p>4 MR. ZONIES: Move to strike.</p> <p>5 Q. (By Ms. Schmid) Dr. Flynn, you also, in</p> <p>6 response to counsel's questions earlier this</p> <p>7 morning, you described the TVT-Secur as a "safer"</p> <p>8 procedure than the TVT-O; do you recall that</p> <p>9 testimony, Dr. Flynn?</p> <p>10 A. I do.</p> <p>11 Q. And can you tell the jury why you</p> <p>12 believe the TVT-S is a safer surgical procedure</p> <p>13 than the TVT-O?</p> <p>14 A. Well, I'll start out just by saying that</p> <p>15 there's less tunnelling required with the</p> <p>16 TVT-Secur. There's less dissection. There's never</p> <p>17 been any reports of bowel or any kind of intestinal</p> <p>18 injury with a mini sling, so that's one reason why</p> <p>19 I would mention that.</p> <p>20 In my own personal experience, I had very</p> <p>21 few complications with this device. I had</p> <p>22 mentioned one mesh exposure and a few cases of</p> <p>23 bladder incomplete emptying.</p> <p>24 I do want to correct what I said earlier</p> <p>25 about five patients that I had to revise. It was</p>	<p>1 record today, Dr. Flynn, you brought with you</p> <p>2 four -- four notebooks to the deposition today,</p> <p>3 correct?</p> <p>4 A. Four notebooks, then there are some</p> <p>5 items that we brought that aren't in the notebook,</p> <p>6 and the USB.</p> <p>7 Q. Okay. What is it that is in the four</p> <p>8 notebooks that you brought with you to today's</p> <p>9 deposition?</p> <p>10 A. Well, starting with notebook one is my</p> <p>11 report, that's an over 50-page document with over a</p> <p>12 hundred references that I spent 14 hours preparing.</p> <p>13 In addition to that, the referenced articles along</p> <p>14 with my reliance list are in these four binders.</p> <p>15 So we got the medical literature, including</p> <p>16 systematic reviews, meta-analyses,</p> <p>17 random-controlled trials, my abstract that I had</p> <p>18 with TVT-Secur, so quite a bit of information.</p> <p>19 Q. Have you, Dr. Flynn, actually read</p> <p>20 yourself all of the articles that are in the</p> <p>21 binders marked 1 through 4 at the deposition today?</p> <p>22 A. I've either read them or have at least</p> <p>23 read the abstract or skimmed these articles at some</p> <p>24 point.</p> <p>25 Q. I'm looking for, now, Dr. Flynn, the</p>
Page 91	Page 93
<p>1 only two. There was five patients in my study that</p> <p>2 had bladder incomplete emptying of which three of</p> <p>3 them had resolved spontaneously, two required</p> <p>4 loosening of the sling, what we call sling lysis.</p> <p>5 None of the patients in the cohort required any</p> <p>6 mesh removal or mesh explantation.</p> <p>7 So I think my own experience with the</p> <p>8 device, the medical literature, the picture that we</p> <p>9 showed earlier looking at the mere size of the</p> <p>10 device I think is very logical why you'd have less</p> <p>11 complications with the device.</p> <p>12 Q. Dr. Flynn, what did you look at to help</p> <p>13 you with your recollection regarding the number of</p> <p>14 sling loosening, or lysis, procedures that you had</p> <p>15 to do on that series of cohorts?</p> <p>16 MR. ZONIES: Object to the form.</p> <p>17 A. During the break, I took the opportunity</p> <p>18 to look at Exhibit 55, which is in my binder, and I</p> <p>19 spent more time looking at the results more</p> <p>20 carefully, so I was speaking purely from memory</p> <p>21 when I was asked about that study. I didn't have</p> <p>22 the study in front of me, so over the break, I went</p> <p>23 back and looked at that number, because it didn't</p> <p>24 sound exactly right to me.</p> <p>25 Q. (By Ms. Schmid) All right. And for the</p>	<p>1 contract that was marked as an exhibit where there</p> <p>2 was a maximum annual sum of \$94,000. Here it is,</p> <p>3 Exhibit Number 7. Do you recall being shown this</p> <p>4 exhibit by Plaintiff's counsel during your</p> <p>5 deposition, Dr. Flynn?</p> <p>6 A. I do.</p> <p>7 Q. And do you recall being asked a question</p> <p>8 about -- bear with me a moment -- at the bottom,</p> <p>9 and there are no page numbers, as far as I could</p> <p>10 see, but that there was a figure of \$94,500 at the</p> <p>11 bottom of this contract with Ethicon and Johnson &amp;</p> <p>12 Johnson; is that correct?</p> <p>13 A. That's the maximum amount that we agreed</p> <p>14 on to be paid in a single year.</p> <p>15 Q. And did Johnson &amp; Johnson and/or Ethicon</p> <p>16 pay you \$94,500 the year that this contract</p> <p>17 pertains to in 2011?</p> <p>18 A. No, not in that year and not in any</p> <p>19 year.</p> <p>20 Q. All right. And do you know, Dr. Flynn,</p> <p>21 how much money you received under the terms of the</p> <p>22 contract that's been marked as Deposition Exhibit 7</p> <p>23 today?</p> <p>24 A. In that particular year?</p> <p>25 Q. Yes, sir.</p>



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<p>1 A. No.</p> <p>2 Q. All right. Was it something less than</p> <p>3 \$94,500?</p> <p>4 A. Significantly less. I know how much I</p> <p>5 was paid between 2004 and 2012 over an eight-year</p> <p>6 time frame, but I don't know, as a breakdown, per</p> <p>7 year.</p> <p>8 Q. Okay. And how much were you paid by</p> <p>9 Ethicon and Johnson &amp; Johnson under consulting</p> <p>10 agreements over an eight-year time period between</p> <p>11 2004 and 2012?</p> <p>12 MR. ZONIES: Object to the form.</p> <p>13 A. So those years are inclusive, so over an</p> <p>14 eight-year period, I was paid \$160,000, so</p> <p>15 approximately \$20,000 a year. I don't remember if</p> <p>16 each year was equal, or how that would spread out,</p> <p>17 but the last time I looked at that, I looked at</p> <p>18 that in preparation for the Perry case, and that</p> <p>19 was the amount that I was able to figure out by</p> <p>20 going through my records, and so it was \$160,000</p> <p>21 over an eight-year period.</p> <p>22 Q. (By Ms. Schmid) All right. Dr. Flynn,</p> <p>23 has the TVT-Secur been studied in</p> <p>24 level-one-evidence randomized control trials?</p> <p>25 A. Yes.</p>	<p>1 something new, something innovative. That's how</p> <p>2 medicine advances.</p> <p>3 So we practice evidence-based when possible.</p> <p>4 When not possible, or when the evidence is weak, or</p> <p>5 the outcomes are mixed, then that's when we look to</p> <p>6 other products and try to advance the science.</p> <p>7 Q. Do the level-one studies that you</p> <p>8 discuss in your expert report or that you had</p> <p>9 produced today, either on the thumb drive or in</p> <p>10 these four notebooks, do they form the basis for</p> <p>11 your opinions provided in the deposition today and</p> <p>12 in your expert report regarding the safety and</p> <p>13 efficacy of the TVT-Secur?</p> <p>14 MR. ZONIES: Object to the form.</p> <p>15 A. They are part of how I form that</p> <p>16 opinion. The other part is based on my education,</p> <p>17 my training, and my own clinical practice as a</p> <p>18 urologist for 15 years at an academic center. I</p> <p>19 rely on all of those things when formulating</p> <p>20 opinions.</p> <p>21 Q. (By Ms. Schmid) Have you, Dr. Flynn,</p> <p>22 personally conducted research into the TVT-Secur?</p> <p>23 A. As we mentioned earlier, I did perform a</p> <p>24 retrospective study of 60 or so patients that we</p> <p>25 reported on in 2009 at the AUGS scientific meeting.</p>
Page 95	Page 97
<p>1 Q. And have you read those level-one RCTs</p> <p>2 regarding the TVT-Secur?</p> <p>3 A. I have.</p> <p>4 Q. And are those studies cited in your</p> <p>5 expert report and/or contained within your reliance</p> <p>6 list?</p> <p>7 MR. ZONIES: Object to the form.</p> <p>8 A. They are. I've cited the Wall study,</p> <p>9 Tomaselli, the Tang and Tincello are just studies</p> <p>10 that immediately come to mind as being either RCTs</p> <p>11 or systematic reviews that I cite in my study -- my</p> <p>12 report. Excuse me.</p> <p>13 Q. (By Ms. Schmid) I apologize. Were you</p> <p>14 finished?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Do you practice evidence-based</p> <p>17 medicine, Dr. Flynn?</p> <p>18 MR. ZONIES: Object to the form.</p> <p>19 A. I do.</p> <p>20 Q. (By Ms. Schmid) And what's that mean?</p> <p>21 A. It means, when possible, if you can make</p> <p>22 a decision based on evidence, that is going to</p> <p>23 guide your practice. There will always be</p> <p>24 exceptions where evidence is not available, or the</p> <p>25 evidence has failed you and you need to try</p>	<p>1 Q. And were the results of your research</p> <p>2 ever published?</p> <p>3 A. The abstract is published. We did not</p> <p>4 publish a formal manuscript, just the abstract.</p> <p>5 Q. And is the data that you arrived at from</p> <p>6 your own personal research into the TVT-Secur part</p> <p>7 of the bases of the opinions that you've expressed</p> <p>8 here today at the deposition as well as those</p> <p>9 expressed in your report?</p> <p>10 MR. ZONIES: Object to the form.</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. (By Ms. Schmid) Have you -- Dr. Flynn,</p> <p>13 have you published any papers in peer-reviewed</p> <p>14 articles regarding the type of mesh that is used in</p> <p>15 the TVT-Secur?</p> <p>16 MR. ZONIES: Object to the form.</p> <p>17 A. I have publications pertaining to TVT</p> <p>18 products, yes. And the most recent article was one</p> <p>19 that we published in an obstetrics journal looking</p> <p>20 at the location of the TVT-O device. That's a mesh</p> <p>21 that is the same mesh that's used in the TVT-Secur</p> <p>22 device.</p> <p>23 Q. (By Ms. Schmid) And is that -- was your</p> <p>24 paper published in a peer-reviewed journal?</p> <p>25 MR. ZONIES: Object to the form.</p>



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<p>1 A. Yes, it's a peer-reviewed journal. It's</p> <p>2 available on PubMed, Index Medicus.</p> <p>3 Q. (By Ms. Schmid) And do you --</p> <p>4 Dr. Flynn, do you serve as a reviewer for medical</p> <p>5 and scientific-based peer-reviewed journals?</p> <p>6 A. Yes. I've done that since the very</p> <p>7 early point in my practice. And I think it's part</p> <p>8 of my role and obligation at a teaching center. I</p> <p>9 served as a reviewer for the Journal of Urology;</p> <p>10 Urology, which is a different journal;</p> <p>11 International Urology and Nephrology; International</p> <p>12 Urogynecology; Neurology and Urodynamics; Canadian</p> <p>13 Journal of Urology. I'm sure there's a few other</p> <p>14 ones I'm missing, but I'm also a content reviewer</p> <p>15 for a number of scientific meetings. So I review</p> <p>16 abstracts, videos and other things that are</p> <p>17 presented at meetings both for the Society of</p> <p>18 Urodynamics and Female Urology for the American</p> <p>19 Urologic Association, for the sectional meetings of</p> <p>20 the AUA.</p> <p>21 I serve as program chair on a number of</p> <p>22 scientific meetings. Currently I'm the program</p> <p>23 chair for two meetings, the Rocky Mountain Urologic</p> <p>24 Society and the South Central Section of the</p> <p>25 American Urological Association. So I was program</p>	<p>1 training and education in the area of treating</p> <p>2 female stress urinary incontinence as a basis for</p> <p>3 the opinions that you have provided today and those</p> <p>4 opinions that you've expressed in your expert</p> <p>5 report on the TVT-Secur?</p> <p>6 MR. ZONIES: Object to form.</p> <p>7 A. That's correct.</p> <p>8 MS. SCHMID: No further questions. Thank</p> <p>9 you, Dr. Flynn.</p> <p>10 THE WITNESS: Thank you.</p> <p>11 EXAMINATION</p> <p>12 BY MR. ZONIES:</p> <p>13 Q. Dr. Flynn, the TVT-S is not the most</p> <p>14 well-studied device, correct?</p> <p>15 A. The TVT mesh is. The device is not.</p> <p>16 Q. That wasn't my question, Doctor. Listen</p> <p>17 to my question.</p> <p>18 A. Okay.</p> <p>19 Q. The TVT-Secur is not well-studied, is</p> <p>20 it?</p> <p>21 MS. SCHMID: I'm going to move to strike</p> <p>22 colloquy --</p> <p>23 A. I'm going to --</p> <p>24 MS. SCHMID: Just a minute.</p> <p>25 -- colloquy of counsel as argumentative.</p>
Page 99	Page 101
<p>1 chair. This weekend coming up, I'll look at 200</p> <p>2 abstracts that were recently submitted to our</p> <p>3 meeting. So I'm very familiar with reviewing</p> <p>4 scientific articles and abstracts.</p> <p>5 Q. Have you relied upon your own research</p> <p>6 and your own peer-reviewed articles regarding</p> <p>7 polypropylene mesh of the type that is used in the</p> <p>8 TVT-Secur in stating your opinions today and those</p> <p>9 provided in your expert report for the TVT-Secur?</p> <p>10 MR. ZONIES: Object to the form.</p> <p>11 A. Yes.</p> <p>12 Q. (By Ms. Schmid) Are all of the opinions</p> <p>13 that you express today, Dr. Flynn, based on a</p> <p>14 reasonable degree of medical and scientific</p> <p>15 certainty?</p> <p>16 A. Yes.</p> <p>17 Q. Are the TVT line of products the most</p> <p>18 studied stress urinary incontinence medical device</p> <p>19 that's ever been sold?</p> <p>20 MR. ZONIES: Object to the form.</p> <p>21 A. That's correct. This is the most widely</p> <p>22 studied device for stress urinary incontinence and</p> <p>23 probably for any disease.</p> <p>24 Q. (By Ms. Schmid) And have you also,</p> <p>25 Dr. Flynn, relied upon your own specialized medical</p>	<p>1 Object to form.</p> <p>2 Go ahead.</p> <p>3 Q. (By Mr. Zonies) Doctor, the TVT-Secur</p> <p>4 device is not the most well-studied incontinence</p> <p>5 device, correct?</p> <p>6 A. The most well-studied?</p> <p>7 Q. Correct.</p> <p>8 A. All right. So it's not the most</p> <p>9 well-studied device.</p> <p>10 Q. The Walsh systematic review that you</p> <p>11 discuss, Doctor, in your report and you mentioned a</p> <p>12 few times today was done in 2011, three years</p> <p>13 before the Cochrane review, correct?</p> <p>14 A. I've got the exact year.</p> <p>15 (Reviewed document.) Okay. Yeah, 2011.</p> <p>16 Q. And that involved one third of the</p> <p>17 number of patients that are reviewed in the</p> <p>18 Cochrane review by Nambiar, correct?</p> <p>19 A. I can't agree to the question the way</p> <p>20 it's stated.</p> <p>21 Q. The Cochrane review was over 3,000</p> <p>22 patients, correct?</p> <p>23 A. 3,000 mini-sling patients, so there's</p> <p>24 multiple slings in that review.</p> <p>25 Q. Are there multiple slings in the Walsh</p>

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<p style="text-align: right;">Page 102</p> <p>1 review? Do you know?</p> <p>2 A. I'll have to go back and look at the</p> <p>3 study.</p> <p>4 MR. ZONIES: I have no further questions.</p> <p>5 Thank you.</p> <p>6 MS. SCHMID: Do you want him to finish -- do</p> <p>7 you want him to provide a response to that last</p> <p>8 question?</p> <p>9 MR. ZONIES: He did. He said he didn't</p> <p>10 know. That's enough. Thanks.</p> <p>11 MS. SCHMID: Well, that's not exactly what</p> <p>12 he said.</p> <p>13 A. (Reviewed document.) Reading from my</p> <p>14 report, the Walsh study, 2011, a thousand patients,</p> <p>15 reference 68, "TVT-Secur mini-sling for stress</p> <p>16 urinary incontinence: a review of outcomes," so I</p> <p>17 believe that that is specific to TVT-Secur.</p> <p>18 Q. (By Mr. Zonies) Were any of the studies</p> <p>19 that are reviewed in Walsh head-to-head studies</p> <p>20 between TVT-Secur and --</p> <p>21 MS. COVINGTON: I think you've used your</p> <p>22 time, because I hit the . . .</p> <p>23 MS. SCHMID: Are we up -- is the two-hour</p> <p>24 time period up?</p> <p>25 MS. COVINGTON: Mm-hmm.</p>	<p style="text-align: right;">Page 104</p> <p>1 I, BRIAN FLYNN, M.D., do hereby certify that</p> <p>2 I have read the foregoing transcript and that the</p> <p>3 same and accompanying amendment sheets, if any,</p> <p>4 constitute a true and complete record of my</p> <p>5 testimony.</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10 _____</p> <p style="text-align: center;">Signature of Deponent</p> <p>11</p> <p>12 ( ) No Amendments</p> <p>13 ( ) Amendments Attached</p> <p>14 Subscribed and sworn to before me</p> <p>15 this _____ day of _____, 2016.</p> <p>16</p> <p>17 Notary Public: _____</p> <p>18 Address: _____</p> <p>19</p> <p>20 My commission expires: _____</p> <p>21 Seal:</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: center;">MLG</p>
<p style="text-align: right;">Page 103</p> <p>1 MS. SCHMID: Okay. Counsel, we're over the</p> <p>2 two-hour time period.</p> <p>3 MR. ZONIES: Okay.</p> <p>4 THE REPORTER: Off the record?</p> <p>5 MR. ZONIES: Yep. Thanks.</p> <p>6 (The deposition was concluded at 1:02 p.m.,</p> <p>7 on Thursday, March 24, 2016.)</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 105</p> <p>1 REPORTER'S CERTIFICATE</p> <p>2 STATE OF COLORADO )</p> <p>3 ) ss.</p> <p>4 COUNTY OF DENVER )</p> <p>5</p> <p>6 I, MELANIE L. GIAMARCO, do hereby certify</p> <p>7 that I am a Registered Professional Reporter and</p> <p>8 Notary Public within the State of Colorado; that</p> <p>9 previous to the commencement of the examination, the</p> <p>10 deponent was duly sworn by me.</p> <p>11 I further certify that this deposition was</p> <p>12 taken in machine shorthand by me at the time and place</p> <p>13 herein set forth, that it was thereafter reduced to</p> <p>14 typewritten form, and that the foregoing constitutes a</p> <p>15 true and correct transcript of the proceedings had.</p> <p>16 I further certify that I am not employed by,</p> <p>17 related to, nor of counsel for any of the parties</p> <p>18 herein, nor otherwise interested in the result of the</p> <p>19 within litigation.</p> <p>20 In witness whereof, I have affixed my</p> <p>21 signature and seal this 29th day of March, 2016.</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: center;">Melanie L. Giamarco Registered Professional Reporter Registered Merit Reporter Certified Realtime Reporter</p> <p>My commission expires: August 25, 2017.</p>

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